AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 85 Wednesday,
No. 232 December 2, 2020

Pages 77343–77984

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 85 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**

General online information **202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Printed on recycled paper.

Contents

Federal Register

Vol. 85, No. 232

Wednesday, December 2, 2020

Agency for Healthcare Research and Quality
NOTICES
Supplemental Evidence and Data Request:
Living Systematic Review on Plant-Based Treatment for Chronic Pain, 77466–77467
Transitions of Care from Pediatric to Adult Services for Children with Special Healthcare Needs, 77463–77465

Agriculture Department
See Animal and Plant Health Inspection Service
See Forest Service

Alcohol, Tobacco, Firearms, and Explosives Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application and Permit for Temporary Importation of Firearms and Ammunition By Nonimmigrant Aliens, 77474

Animal and Plant Health Inspection Service
NOTICES
Petition to Manufacture Foot-and-Mouth Disease Vaccine in the United States, 77425–77426

Centers for Disease Control and Prevention
NOTICES
Meetings:
Advisory Committee on Immunization Practices, 77467–77468
Disease, Disability, and Injury Prevention and Control Special Emphasis Panel, 77467

Centers for Medicare & Medicaid Services
RULES
Medicare and Medicaid Programs:
Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 77898–77949
Medicare Program:
Modernizing and Clarifying the Physician Self-Referral Regulations, 77492–77682
Specialty Care Models to Improve Quality of Care and Reduce Expenditures; Correction, 77404–77406

Civil Rights Commission
NOTICES
Meetings:
Delaware Advisory Committee, 77427

Commerce Department
See Foreign-Trade Zones Board
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration

Commodity Futures Trading Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Real Time Public Reporting, 77437–77439
Swap Data Recordkeeping and Reporting Requirements, 77435–77437

Comptroller of the Currency
RULES
Temporary Asset Thresholds, 77345–77364

Defense Department
See Navy Department
NOTICES
Arms Sales, 77439–77454

Defense Nuclear Facilities Safety Board
NOTICES
Senior Executive Service:
Performance Review Board, 77455–77456

Education Department
NOTICES
Request for Information:
Expanding Work-Based Learning Opportunities for Youth, 77456–77459

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
RULES
Financial Responsibility Requirements under CERCLA:
Facilities in the Electric Power Generation, Transmission, and Distribution Industry; the Petroleum and Coal Products Manufacturing Industry; and the Chemical Manufacturing Industry, 77384–77404
Test Methods and Performance Specifications for Air Emission Sources; Correction, 77384
NOTICES
Meetings:
Clean Air Act Advisory Committee, 77461–77462

Farm Credit Administration
RULES
Amortization Limits; Correction, 77364–77365
NOTICES
Meetings; Sunshine Act, 77462

Federal Deposit Insurance Corporation
RULES
Temporary Asset Thresholds, 77345–77364
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Survey of Household Use of Banking and Financial Services, 77462–77463

Federal Energy Regulatory Commission
NOTICES
Combined Filings, 77459–77461
Request for Temporary Waiver:
Roaring Fork Midstream, LLC, 77460

Federal Reserve System
RULES
Temporary Asset Thresholds, 77345–77364

Fish and Wildlife Service
PROPOSED RULES
Endangered and Threatened Wildlife and Plants:
Threatened Species Status for Pinus albicaulis (Whitebark Pine) with Section 4(d) Rule, 77408–77424

Food and Drug Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 77469
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Infant Formula Requirements, 77469–77472
Amendment of Temporary Marketing Permit:
Canned Pacific Salmon Deviating From Identity Standard, 77468–77469

Foreign-Trade Zones Board
NOTICES
Approval of Subzone Expansion:
ASML US, LLC Wilton, CT, 77427

Forest Service
NOTICES
2020 Thunder Basin National Grassland Plan Amendment:
Medicine Bow-Routt National Forests and Thunder Basin National Grassland; Wyoming, 77426–77427

Health and Human Services Department
See Agency for Healthcare Research and Quality
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See Inspector General Office, Health and Human Services Department
See National Institutes of Health
NOTICES
Request for Information:
HIV National Strategic Plan 2021–2025, 77472–77473

Industry and Security Bureau
NOTICES
Condition of the Public Health Industrial Base and Recommend Policies and Actions to Strengthen the Public Health Industrial Base to Ensure Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States; Request for Public Comments, 77428–77430

Inspector General Office, Health and Human Services Department
RULES
Medicare and State Health Care Programs:
Fraud and Abuse; Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 77684–77895

Interior Department
See Fish and Wildlife Service

Internal Revenue Service
RULES
Statutory Limitations on Like-Kind Exchanges, 77365–77383
Unrelated Business Taxable Income Separately Computed for Each Trade or Business, 77952–77984
NOTICES
Publication of the Tier 2 Tax Rates, 77486

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Advance Notification of Sunset Review, 77431
Opportunity to Request Administrative Review, 77431–77434
Scope Rulings, 77434–77435

International Trade Commission
NOTICES
Investigations; Determinations, Modifications, and Rulings, etc.:
Forged Steel Fittings from India and Korea, 77473

Justice Department
See Alcohol, Tobacco, Firearms, and Explosives Bureau
NOTICES
Proposed Modification to Consent Decree:
CERCLA, 77474–77475

National Institutes of Health
NOTICES
Meetings:
National Institute on Alcohol Abuse and Alcoholism, 77473

National Oceanic and Atmospheric Administration
RULES
Fisheries of the Exclusive Economic Zone Off Alaska:
Reallocation of Pacific Cod in the Central Regulatory Area of the Gulf of Alaska, 77406–77407
Pacific Island Fisheries:
2020 Territorial Longline Bigeye Tuna Catch Limits for the Commonwealth of the Northern Mariana Islands; Correction, 77406

Navy Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 77454–77455

Presidential Documents
PROCLAMATIONS
Special Observances:
Thanksgiving Day (Proc. 10121), 77343–77344

Securities and Exchange Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 77475–77477
Application:
Deregistration under the Investment Company Act of 1940, 77477–77478

Social Security Administration
NOTICES
Privacy Act; System of Records, 77478–77480

State Department
NOTICES
Delegation of Authority, 77480–77481
Request for Information:
2021 Trafficking in Persons Report, 77481–77486

Surface Transportation Board
NOTICES
Acquisition and Operation Exemption:
West Virginia State Rail Authority; The Elk River Railroad, Inc., 77486

Treasury Department
See Comptroller of the Currency
See Internal Revenue Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Request for Transfer of Property Seized/Forfeited by a Treasury Forfeiture Fund Participating Agency, 77486–77487

Veterans Affairs Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Chapter 31 Request for Assistance, 77488–77489
Expanded Access to Non-VA Care through the MISSION Act: Veterans Community Care Program, 77487–77488

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 77492–77682

Part III
Health and Human Services Department, Inspector General Office, Health and Human Services Department, 77684–77895

Part IV
Health and Human Services Department, Centers for Medicare & Medicaid Services, 77898–77949

Part V
Treasury Department, Internal Revenue Service, 77952–77984

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Proclamations:

10121 77343

12 CFR

3 77345
4 77345
52 77345
208 77345
211 77345
212 77345
217 77345
225 77345
235 77345
238 77345
304 77345
324 77345
337 77345
347 77345
348 77345
614 77364

26 CFR

1 (2 documents) 77365, 77952
602 77952

40 CFR

63 77384
320 77384

42 CFR

411 77491
486 77898
512 77404
1001 77684
1003 77684

50 CFR

665 77406
679 77406

Proposed Rules:

17 77408

Federal Register
Vol. 85, No. 232
Wednesday, December 2, 2020

Presidential Documents

Title 3—

The President

Proclamation 10121 of November 25, 2020

Thanksgiving Day, 2020

By the President of the United States of America

A Proclamation

On Thanksgiving Day, we thank God for the abundant blessings in our lives. As we gather with family and friends to celebrate this season of generosity, hope, and gratitude, we commemorate America's founding traditions of faith, family, and friendship, and give thanks for the principles of freedom, liberty, and democracy that make our country exceptional in the history of the world.

This November marks 400 years since the Mayflower and its passengers faced the unknown and set sail across the Atlantic Ocean. Propelled by hope for a brighter future, these intrepid men and women endured two long months at sea, tired and hungry, to arrive in a new world full of potential. In the winter weather that greeted their arrival, they lost nearly half of their fellow travelers to exposure, disease, and starvation. Despite unimaginable hardships, these first Americans nevertheless remained firm in their faith and unwavering in their commitment to their dreams. They forged friendships with the Wampanoag Tribe, fostered a spirit of common purpose among themselves, and trusted in God to provide for them. The following year, they celebrated a successful harvest alongside their Native American neighbors—the first Thanksgiving. This seminal event in the history of our Nation is a continual reminder of the power of faith, love, perseverance, prayer, and fellowship.

The Mayflower's arrival to the New World in 1620 also marks the arrival of the first seeds of democracy to our land. Absent the rule of a monarch in an uncharted wilderness, these early settlers resolved to create their own government through what is known as the Mayflower Compact. Defined by majority rule through elected leaders responsible for creating ''just and equal laws,'' the Mayflower Compact represents the first chapter in the long tradition of self-determination and rule of law in America. One hundred and fifty-six years later, our Nation's Founding Fathers resolved to break free from England, building upon the Mayflower Compact to establish an enduring government whose authority came solely ''from the consent of the governed.''

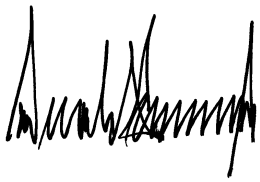
This year, as our Nation continues to combat the coronavirus pandemic, we have once again joined together to overcome the challenges facing us. In the midst of suffering and loss, we are witnessing the remarkable courage and boundless generosity of the American people as they come to the aid of those in need, reflecting the spirit of those first settlers who worked together to meet the needs of their community. First responders, medical professionals, essential workers, neighbors, and countless other patriots have served and sacrificed for their fellow Americans, and the prayers of our people have once again lifted up our Nation, providing comfort, healing, and strength during times of uncertainty. Despite unprecedented challenges, we have not faltered in the face of adversity. To the contrary, we have leveraged our strengths to make significant breakthroughs that will end this crisis, rebuilding our stockpiles, revamping our manufacturing capabilities, and developing groundbreaking therapeutics and life-saving vaccines on record-shattering timeframes.

During this season of gratitude, we also acknowledge those who cannot be with their families. This includes the brave American patriots of our Armed Forces who selflessly defend our sacred liberty at home and abroad. And we pause to remember the sacrifices of our law enforcement personnel and first responders. We are deeply grateful for all those who remain on watch over the holidays and keep us safe as we celebrate and give thanks for the blessings in our lives.

This Thanksgiving, we reaffirm our everlasting gratitude for all that we enjoy, and we commemorate the legacy of generosity bestowed upon us by our forbearers. Although challenges remain, we will never yield in our quest to live up to the promise of our heritage. As we gather with our loved ones, we resolve with abiding faith and patriotism to celebrate the joys of freedom and cherish the hope and peace of a brighter future ahead.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim Thursday, November 26, 2020, as a National Day of Thanksgiving. I encourage all Americans to gather, in homes and places of worship, to offer a prayer of thanks to God for our many blessings.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fifth day of November, in the year of our Lord two thousand twenty, and of the Independence of the United States of America the two hundred and forty-fifth.



[FR Doc. 2020–26629
Filed 12–1–20; 8:45 am]
Billing code 3295–F1–P

Rules and Regulations

Federal Register

Vol. 85, No. 232

Wednesday, December 2, 2020

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 3, 4, and 52

[Docket ID OCC–2020–0044]

RIN 1557–AF06

FEDERAL RESERVE SYSTEM

12 CFR Parts 208, 211, 212, 217, 225, 235, and 238

[Docket No. R–1731]

RIN 7100–AG01

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 304, 324, 337, 347, and 348

RIN 3064–AF67

Temporary Asset Thresholds

AGENCY: Office of the Comptroller of the Currency, Treasury (OCC); Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Interim final rule, request for public comment.

SUMMARY: To mitigate temporary transition costs on banking organizations related to the coronavirus disease 2019 (COVID event), the OCC, Board, and the FDIC (together, the agencies) are issuing an interim final rule to permit national banks, savings associations, state banks, bank holding companies, savings and loan holding companies, and U.S. branches and agencies of foreign banking organizations with under $10 billion in total assets as of December 31, 2019, (community banking organizations) to use asset data as of December 31, 2019, in order to determine the applicability of various regulatory asset thresholds during calendar years 2020 and 2021. For the same reasons, the Board is temporarily revising the instructions to a number of its regulatory reports to provide that community banking organizations may use asset data as of December 31, 2019, in order to determine reporting requirements for reports due in calendar years 2020 or 2021.

DATES:

Effective date: This rule is effective on December 2, 2020.

Comment date: Comments must be received on or before February 1, 2021.

ADDRESSES: Comments should be directed to:

OCC: You may submit comments to the OCC by any of the methods set forth below. Commenters are encouraged to submit comments through the Federal eRulemaking Portal, if possible. Please use the title ''Temporary Asset Thresholds'' to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal—Regulations.gov Classic or Regulations.gov Beta.*

Regulations.gov Classic: Go to *https://www.regulations.gov/.* Enter ''Docket ID OCC–2020–0044'' in the Search Box and click ''Search.'' Click on ''Comment Now'' to submit public comments. For help with submitting effective comments, please click on ''View Commenter's Checklist.'' Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov*, including instructions for submitting public comments.

Regulations.gov Beta: Go to *https://beta.regulations.gov/* or click ''Visit New *Regulations.gov* Site'' from the *Regulations.gov* classic homepage. Enter ''Docket ID OCC–2020–0044'' in the Search Box and click ''Search.'' Public comments can be submitted via the ''Comment'' box below the displayed document information or click on the document title and click the ''Comment'' box on the top-left side of the screen. For help with submitting effective comments, please click on ''Commenter's Checklist.'' For assistance with the *Regulations.gov* Beta site, please call (877) 378–5457 (toll free) or (703) 454–9859 Monday–Friday, 9 a.m.–5 p.m. ET or email to *regulations@erulemakinghelpdesk.com.*

- *Mail:* Chief Counsel's Office, Attn: Comment Processing, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

Instructions: You must include ''OCC'' as the agency name and ''Docket ID OCC–2020–0044'' in your comment.

In general, the OCC will enter all comments received into the docket and publish the comments on the *Regulations.gov* website without change, including any business or personal information provided such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this rulemaking action by the following methods:

- *Regulations.gov Classic or Regulations.gov Beta:*

Regulations.gov Classic: Go to *https://www.regulations.gov/.* Enter ''Docket ID OCC–2020–0044'' in the Search box and click ''Search.'' Click on ''Open Docket Folder'' on the right side of the screen. Comments and supporting materials can be viewed and filtered by clicking on ''View all documents and comments in this docket'' and then using the filtering tools on the left side of the screen. Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov*. The docket may be viewed after the close of the comment period in the same manner as during the comment period.

Regulations.gov Beta: Go to *https://beta.regulations.gov/* or click ''Visit New *Regulations.gov* Site'' from the *Regulations.gov* classic homepage. Enter ''Docket ID OCC 2020–0044'' in the Search Box and click ''Search.'' Click on the ''Comments'' tab. Comments can be viewed and filtered by clicking on the ''Sort By'' drop-down on the right side of the screen or the ''Refine Results'' options on the left side of the screen. Supporting Materials can be viewed by clicking on the ''Documents'' tab and filtered by clicking on the ''Sort By'' drop-down on the right side of the

screen or the ''Refine Results'' options on the left side of the screen. For assistance with the *Regulations.gov* Beta site please call (877) 378–5457 (toll free) or (703) 454–9859 Monday–Friday, 9 a.m.–5 p.m. ET or email *regulations@erulemakinghelpdesk.com.* The docket may be viewed after the close of the comment period in the same manner as during the comment period.

Board: You may submit comments, identified by Docket No. R–1731 and RIN No. 7100–AG01, by any of the following methods:

- *Agency Web Site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *E-mail: regs.comments@federalreserve.gov.* Include docket number and RIN in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons or to remove sensitive PII at the commenter's request. Public comments may also be viewed electronically or in paper form in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: You may submit comments on the notice of proposed rulemaking using any of the following methods:

- *Agency Website: https://www.fdic.gov/regulations/laws/federal.* Follow the instructions for submitting comments on the agency website.
- *Email: comments@fdic.gov.* Include RIN 3064–AF67 on the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street NW building (located on F Street) on business days between 7 a.m. and 5 p.m.
- *Public Inspection:* All comments received, including any personal information provided, will be posted generally without change to *https://www.fdic.gov/regulations/laws/federal.*

FOR FURTHER INFORMATION CONTACT:

OCC: Alison MacDonald, Special Counsel, or Kevin Korzeniewski, Counsel, Chief Counsel's Office, (202) 649–5490.

Board: Juan Climent, Assistant Director, (202) 872–7526, Eric Kennedy, Assistant Director, (202) 263–4887, Nancy J. Oakes, Manager, (202) 452–3413, Teresa Scott, Manager, (202) 973–6114, Naima Jefferson, Lead Financial Institution Policy Analyst, (202) 912–4613, Daniel Newman, Senior Data Governance Analyst, (202) 973–7409, Senait Kahsay, Senior Financial Institution Policy Analyst II, (202) 245–4209, Joseph Willcox, Senior Financial Institution Policy Analyst II, (202) 452–3663, Division of Supervision and Regulation; Laurie Schaffer, Deputy General Counsel (202) 452–2272, Benjamin McDonough, Associate General Counsel, (202) 973–7432, Jonah Kind, Counsel (202) 452–2045, Justyna Bolter, Senior Attorney (202) 452–2686, Christopher Danello, Attorney, (202) 736–1960, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. For users of Telecommunication Device for the Deaf (TDD), (202) 263–4869.

FDIC: Rae-Ann Miller, Associate Director, Risk Management Policy, (202) 898–3898, Bobby R. Bean, Associate Director, Capital Markets, (202) 898–6705; William Piervincenzi, Supervisory Counsel, (202) 898–6957, Nefretete A. Smith, Counsel, (202) 898–6851, Michael B. Phillips, Counsel, (202) 898–3581, Jennifer M. Jones, Counsel, (202) 898–6768, *jennjones@fdic.gov,* Supervision and Legislation Branch, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), (800) 925–4618.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
II. Discussion
  A. Interim Final Rule
  B. Reservation of Authority
  C. Regulatory Reporting Changes
III. Request for Comment
IV. Administrative Law Matters
  A. Administrative Procedure Act
  B. Congressional Review Act
  C. Paperwork Reduction Act
  D. Regulatory Flexibility Act
  E. Riegle Community Development and Regulatory Improvement Act of 1994
  F. Unfunded Mandates Reform Act of 1995
  G. Use of Plain Language

I. Background

In light of strains in economic conditions related to the COVID event and stress in U.S. financial markets, the agencies have taken a number of actions intended to: (i) Restore market functioning and support the flow of credit to households, businesses, and communities and (ii) increase flexibility and reduce regulatory reporting burden. Among those actions, the agencies have issued a number of rules and supervisory guidance communications designed to mitigate the consequences of the COVID event and to facilitate the safe and effective operations of banking organizations.[1]

Community banking organizations have played an instrumental role in the nation's financial response to the COVID event, and many have experienced significant balance sheet growth as a result of the COVID event and the policy response to the event. Policies encouraging banks to work with their customers, such as the Small Business Administration's (SBA's) Paycheck Protection Program (PPP)[2] and the interagency statement encouraging financial institutions to work with borrowers affected by the COVID event,[3] have resulted in much-needed emergency liquidity being offered to small businesses, including, but not limited to, individuals operating sole proprietorships or acting as independent contractors, certain franchisees, nonprofit corporations, veterans organizations, Tribal businesses, and households. As a result, during the COVID event many community banking organizations have experienced an unexpected and sharp increase in assets, swelling their balance sheets in some cases by more than 25 percent.[4] Much of this growth,

[1] *See* ''Supervisory and Regulatory Actions in Response to COVID–19,'' available at *https://www.federalreserve.gov/supervisory-regulatory-action-response-covid-19.htm.;* ''COVID–19 (Coronavirus),'' available at *https://occ.gov/topics/supervision-and-examination/bank-operations/covid-19-information/convid-19-info-index.html;* ''Coronavirus (COVID–19) Information for Bankers and Consumers,'' available at *https://www.fdic.gov/coronavirus/. See also* ''The FDIC Approves Interim Final Rule to Provide Temporary Relief from Part 363 Audit and Reporting Requirements,'' available at *https://www.fdic.gov/news/financial-institution-letters/2020/fil20099.html* and Final Rule Mitigating the Deposit Insurance Assessment Effect of Participation in the Paycheck Protection Program (PPP), the PPP Liquidity Facility, and the Money Market Mutual Fund Liquidity Facility at *https://www.fdic.gov/news/financial-institution-letters/2020/fil20063.html.*

[2] The SBA's PPP was created under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) in response to market distress caused by the COVID–19 event. Public Law 116–136, 134 Stat. 281.

[3] ''Revised Interagency Statement on Loan Modifications by Financial Institutions Working with Customers Affected by the Coronavirus'' (Apr. 7, 2020), available at *https://www.occ.gov/news-issuances/news-releases/2020/nr-ia-2020-50a.pdf.*

[4] Data derived from the Consolidated Reports of Condition and Income (Call Report) and Financial

particularly that related to participation in PPP, is expected to be temporary.

PPP loans are a special asset class of government-guaranteed assets designed to incentivize businesses to keep workers on payroll. To encourage lending to small businesses through the SBA's PPP, the Board established the PPP Liquidity Facility on April 9, 2019.[5] Under the PPP Liquidity Facility, each of the Federal Reserve Banks may extend non-recourse loans to banking organizations that pledge PPP loans, which continue to be assets on the balance sheets of banking organizations, as collateral.[6] The last day for lenders to make a PPP loan was August 8, 2020,[7] and depending on SBA determinations, a significant amount of PPP debt forgiveness may occur in the fourth calendar quarter of 2020 or early in the first calendar quarter of 2021. However, as a result of the PPP loan forgiveness process, many PPP-related assets remain on community banking organizations' balance sheets. The SBA recently released a simpler loan forgiveness application for PPP loans of $50,000 or less, which will likely result in PPP-related assets being removed from community banking organization's balance sheets at a faster rate.[8]

According to SBA statistics, collectively all lenders with less than $10 billion in assets originated 2,745,204 PPP loans totaling $233.7 billion, which buttressed the paychecks of more than 26 million American workers and represented more than 52.6 percent of the number of loans originated under the program.[9] This data suggests that the percentage of PPP loans originated by community banking organizations far exceeds those organizations' market share as a percentage of total banking system assets illustrating the outsized impact that participation in the PPP has had on community banking organizations.[10]

Community banking organizations are subject to a wide range of statutory requirements, regulations, and reporting requirements predicated on their risk profile and asset size.[11] Due to their response to the COVID event, many community banking organizations have been, or may soon be, pushed over an asset threshold that could subject them to additional regulation or to additional reporting requirements.[12] In the absence of regulatory burden relief, complying with these new or more stringent regulatory standards, especially if the community banking organization's assets are expected to be above a threshold for a limited time, would impose significant transition and compliance costs on community banking organizations. This interim final rule gives community banking organizations more time to either reduce their balance sheets by shedding temporary growth, or to prepare for higher regulatory and reporting standards.

II. Discussion

A. Interim Final Rule

A number of regulations contain asset-based thresholds that determine whether a banking organization is required to comply with a given regulatory requirement or provide a mandatory regulatory report, or whether a banking organization is otherwise eligible for a particular regulatory treatment. Asset-based regulatory thresholds are meant to ensure that the regulatory requirements applicable to a banking organization are appropriate, given the banking organization's likely risk profile and, in some cases, the potential risk that the banking organization poses to U.S. financial stability.

As discussed above, many community banking organizations have experienced an unexpected and sharp increase in assets since the beginning of the COVID event. This rapid growth has caused the assets of certain community banking organizations to rise above certain asset-based thresholds in the agencies' regulations, and may cause other community banking organizations to do so in the near future. As noted, much of this growth, especially growth related to PPP lending, is likely to be temporary, and the increase in assets currently held by a community banking organization may not reflect a change in the organization's longer-term risk profile.

In the absence of regulatory burden relief, community banking organizations that experience an increase in assets above one or more regulatory thresholds would face significant transition costs necessary to comply with new or more stringent regulatory and reporting standards. Given the rapid and unexpected nature of community banking organization asset growth in 2020, many community banking organizations are unlikely to have planned for these transition costs. Further, to the extent this asset growth is temporary, it does not reflect changes in community banking organizations' risk profiles, and many community banking organizations that cross above asset-based regulatory thresholds could fall back below the thresholds. Additionally, community banking organizations that are approaching certain asset thresholds in the agencies' regulations may become reluctant to continue lending if this would subject them to new or more stringent regulatory and reporting standards. Therefore, the agencies believe it is appropriate to provide temporary regulatory burden relief to community banking organizations that have risen above, or will rise above, certain asset-based regulatory thresholds. The relief should promote further lending and avoid potentially temporary, but significant, transition costs that community banking organizations would otherwise face to comply with new standards.

In order to provide this regulatory burden relief, the agencies are issuing this interim final rule to temporarily change, for a number of asset-based regulatory thresholds, the date as of when a community banking organization measures its assets for the purpose of determining whether it exceeds the threshold (referred to as the ''measurement date''). Specifically, the interim final rule will permit community banking organizations, through December 31, 2021, to determine the applicability of certain asset-based regulatory thresholds using asset data as of December 31, 2019, if the organization's assets as of that date were less than its assets on the date as

Statements for Holding Companies (FR Y–9C) data December 31, 2019 to June 30, 2020.

[5] *See https://www.federalreserve.gov/newsevents/pressreleases/monetary20200409a.htm.*

[6] *See* Paycheck Protection Program Liquidity Facility Term Sheet, available at *https://www.federalreserve.gov/newsevents/pressreleases/files/monetary20200728a7.pdf.*

[7] U.S. Small Business Administration, ''Notice: Paycheck Protection Program closed August 8, 2020,'' available at *https://www.sba.gov/funding-programs/loans/coronavirus-relief-options/paycheck-protection-program#section-header-0.*

[8] U.S. Small Business Administration, ''SBA and Treasury Announce Simpler PPP Forgiveness for Loans of $50,000 or Less'', October 8, 2020 available at *https://www.sba.gov/article/2020/oct/08/sba-treasury-announce-simpler-ppp-forgiveness-loans-50000-or-less.*

[9] U.S. Small Business Administration, ''Paycheck Protection Program (PPP) Report: Approvals through 08/08/2020,'' available at *https://home.treasury.gov/system/files/136/SBA-Paycheck-Protection-Program-Loan-Report-Round2.pdf.*

[10] As of the June 30, 2020, approximately 80 percent of depository institutions with assets less than $10 billion reported PPP loans on their Call Report.

[11] The agencies recognize there are some guidance documents that include asset-based thresholds of $10 billion or below. In these instances, the agencies are confirming that these thresholds are exemplary only and not suggestive of requirements. For the reasons discussed above, the agencies will take the same perspective on asset-based thresholds in guidance as they are taking with regard to asset-based regulatory thresholds.

[12] Based on data as of June 30, 2020, the agencies estimate that around 44 holding companies and 582 community banks crossed a regulatory threshold set at $10 billion or less.

of which the applicability of a given threshold would normally be determined. This means that asset growth in 2020 or 2021 will not trigger new regulatory requirements for these community banking organizations until January 1, 2022, at the earliest. This temporary regulatory burden relief reflects that much of the asset growth since the start of the COVID event, especially growth related to PPP lending, is generally expected to be temporary in nature and therefore likely does not reflect changes in community banking organizations' risk profile.

The agencies are limiting the regulatory burden relief in this interim final rule to banking organizations that had less than $10 billion in assets as of December 31, 2019. Banking organizations with under $10 billion in assets likely have fewer resources available to prepare and comply with previously unanticipated regulatory requirements, especially during a time of economic uncertainty and disruption. Further, as discussed above, community banking organizations have originated a disproportionately large percentage of PPP loans, as compared with the organizations' market share; therefore, as compared to larger organizations, a larger portion of any increase in asset size at community banking organizations is likely to be temporary, and is therefore less likely to reflect a change in an organization's risk profile or business activities.

This temporary regulatory burden relief applies to the following asset-based regulatory thresholds: [13]

Regulation	Regulatory threshold effect	Asset-based threshold [14]	Rule location	Asset measurement date (prior to January 1, 2022)	Asset measurement date (for requirements in 2022)
OCC: Capital Adequacy Standards (Part 3). Board: Capital Adequacy of Bank Holding Companies, Savings and Loan Holding Companies, and State Member Banks (Regulation Q). FDIC: Capital Adequacy of FDIC- Supervised Institutions.	Eligibility for community bank leverage ratio framework.	$10 billion in total consolidated assets.	OCC: 12 CFR 3.12 Board: 12 CFR 217.12 FDIC: 12 CFR 324.12	December 31, 2019, or the end of the most recent calendar quarter, whichever results in a lower amount.	End of the most recent calendar quarter.
Board: Debit Card Interchange Fees and Routing (Regulation II).	Exemption for small issuers.	$10 billion in assets	Board: 12 CFR 235.5(a)	December 31, 2019, or December 31, 2020, whichever results in a lower amount.	December 31, 2021.
Board: Management Official Interlocks (Regulation L). FDIC: Management Official Interlocks.	Exemption from prohibition on service as a "management official" of multiple institutions.	$10 billion in total assets	Board: 12 CFR 212.3(c) FDIC: 12 CFR 348.3(c)	December 31, 2019, or the end of the depository organization's most recent fiscal year, whichever results in a lower amount.	End of the most recent fiscal year.
	Exemption for honorary or advisory directors from definition of "management official".	$100 million in total assets.	Board: 12 CFR 212.2(j)(1) FDIC: 12 CFR 348.2(k)(1).		
	Exemption from relevant metropolitan statistical area prohibition.	$50 million in total assets	Board: 12 CFR 212.3(b) FDIC: 12 CFR 348.3(b).		
Board: Savings and Loan Holding Companies (Regulation LL).	Interlocks—Major asset prohibition.	$10 billion	Board: 12 CFR 238.93(c)	December 31, 2019, or the end of the organization's most recent fiscal year, whichever results in a lower amount.	End of the most recent fiscal year.
	Audit requirement for safety and soundness purposes.	$500 million	Board: 12 CFR 238.5(b)	December 31, 2019, or end of the organization's most recent fiscal year, whichever results in a lower amount.	End of the most recent fiscal year.
	Informational requirements for acquisition of a company.	$150 million	Board: 12 CFR 238.53(c)(2)(iii)–(iv).	December 31, 2019, or the end of the most recent calendar quarter, whichever results in a lower amount.	End of the most recent calendar quarter.

[13] This interim final rule does not address the exemption in the Board's Regulation H from certain flood insurance escrow requirements for qualifying state member banks (less than $1 billion in assets as of December 31 of either of the two prior calendar years, provided other conditions are also met), 12 CFR 208.25(e)(3), or the provision in the Board's Regulation BB defining small bank and intermediate small bank for purposes of determining applicable Community Reinvestment Act evaluation procedures. As currently defined in Regulation BB: a small bank is a bank that, as of December 31 of either of the prior two calendar years, had assets of less than $1.305 billion; an intermediate small bank is a small bank with assets of at least $326 million as of December 31 of both of the prior two calendar years and less than $1.305 billion as of December 31 of either of the prior two calendar years; and a large bank is a bank with assets of at least $1.305 billion as of December 31 of both of the prior two calendar years, 12 CFR 228.12(u)(1). As indicated, the asset-based thresholds in these provisions take into account assets as of the end of the two previous calendar years. Therefore, the earliest that a bank with assets that did not exceed one of these thresholds as of December 31, 2019, could exceed the threshold is January 1, 2022. As a result, consistent with this interim final rule, asset growth in 2020 or 2021 will not trigger new regulatory requirements until January 1, 2022, at the earliest. For similar reasons, the interim final rule does not adjust thresholds in the OCC and the FDIC's flood insurance escrow rule at 12 CFR 22.5(c) (OCC) and 12 CFR 339.5(c) (FDIC) and Community Reinvestment Act regulatory thresholds for small banks and intermediate banks at 12 CFR part 25 (OCC) and 12 CFR 345 (FDIC). The OCC also is not adjusting thresholds for depository institution management interlocks at 12 CFR part 26, as this part already permits any affected bank to request a waiver related to unanticipated asset growth.

[14] This interim final rule only provides temporary relief with regard to the measurement date of assets. Other criteria that apply to certain of the affected regulatory provisions remain in effect, and the measurement date for other quantities has not been changed by this interim final rule.

Regulation	Regulatory threshold effect	Asset-based threshold [14]	Rule location	Asset measurement date (prior to January 1, 2022)	Asset measurement date (for requirements in 2022)
	Interlocks—Exemption for honorary or advisory directors from definition of ''management official''.	$100 million	Board: 12 CFR 238.92(j)(1)	December 31, 2019, or the end of the organization's most recent fiscal year, whichever results in a lower amount.	End of the most recent fiscal year.
	Interlocks—Exemption from relevant metropolitan statistical area prohibition.	$50 million	Board: 12 CFR 238.93(b)	December 31, 2019, or the end of the organization's most recent fiscal year, whichever results in a lower amount.	End of the most recent fiscal year.
OCC: Regulatory Reporting (Part 52). Board: Membership of State Banking Institutions in the Federal Reserve System (Regulation H) FDIC: Forms, Instructions, and Reports	Eligibility for reduced reporting of the Consolidated Reports of Condition and Income (Call Report).	$5 billion	OCC: 12 CFR 52.2 Board: 12 CFR 208.122(b) FDIC: 12 CFR 304.12(a)	December 31, 2019, or June 30, 2020, whichever results in a lower amount.	June 30, 2021.
OCC: Organization and Functions (Part 4, Subpart A). Board: Membership of State Banking Institutions in the Federal Reserve System (Regulation H). FDIC: Unsafe and Unsound Bank Practices.	Eligibility for 18-month examination cycle.	$3 billion	OCC: 12 CFR 4.6(b) Board: 12 CFR 208.64(b) FDIC: 12 CFR 337.12(b)	December 31, 2019, or the end of the most recent calendar quarter, whichever results in a lower amount.	End of most recent calendar quarter.
Board: Membership of State Banking Institutions in the Federal Reserve System (Regulation H).	Eligibility for streamlined method of compliance with the reporting requirements of the Securities and Exchange Commission.	$150 million	12 CFR 208.36(b)	December 31, 2019, or the end of the bank's most recent fiscal year, whichever results in a lower amount.	End of the most recent fiscal year.
Bank Holding Companies and Change in Bank Control (Regulation Y).	Various thresholds in the Board's rules regarding bank holding companies and change in bank control (Regulation Y) concerning filing requirements and permissible activities.	$3 billion, $300 million, $150 million, and $50 million.	12 CFR 225.4(b)(2)(iii)(A)–(B), 225.14(a)(1)(v)(A)(1)–(2), 225.14(a)(1)(vi), 224.14(c)(6)(ii), 225.17(a)(6), 225.23(a)(1)(iii)(A)(1)–(2), 225.23(c)(5)(ii), 225.24(a)(2)(iv)–(v), 225.28(b)(11)(vi), and Appendix C.	December 31, 2019, or the end of the most recent calendar quarter, whichever results in a lower amount.	Normally applicable asset measurement date.
OCC: Organization and Functions (Part 4, Subpart A). Board: International Banking Operations (Regulation K). FDIC: International Banking.	Eligibility for an 18-month examination cycle for U.S. branches and agencies of foreign banks.	$3 billion	OCC: 12 CFR 4.7(b) Board: 12 CFR 211.26(c)(2) FDIC: 12 CFR 347.211(b)	December 31, 2019, or the end of the most recent calendar quarter, whichever results in a lower amount.	End of most recent calendar quarter.

As a result of this temporary regulatory burden relief, a community banking organization that was below one of the above-listed asset thresholds as of December 31, 2019, generally will be deemed to remain below that threshold through the end of 2021, plus any applicable transition period provided by the regulation. For example, the Board's rules regarding debit card interchange fees and routing include an exemption for small issuers, which provides that a debit card issuer is not required to comply with certain requirements with respect to an electronic debit transaction if the issuer holds the account that is debited and the issuer, together with its affiliates, has assets of less than $10 billion as of the end of the calendar year preceding the date of the electronic debit transaction.[15] Pursuant to this interim final rule, an issuer that, together with its affiliates, had assets of $9.9 billion as of December 31, 2019, $10.1 billion as of December 30, 2020, and $10.1 billion as of December 31, 2021, would be deemed to remain below the $10 billion threshold for purposes of this rule through the end of 2021, at which point the six-month transition period provided by 12 CFR 235.5(a)(3) would begin. Therefore, this issuer would not be required to comply with the Board's rules regarding debit card interchange fees and routing until July 1, 2022.

The temporary regulatory burden relief provided by this interim final rule applies through the end of 2021, so that a community banking organization within the scope of the temporary regulatory burden relief will not be required to comply with the regulatory or reporting requirements covered by this interim final rule until the beginning of 2022 (plus any applicable transition period),[16] at the earliest,

[15] 12 CFR 235.5(a).

[16] *See* 12 CFR 3.12(c) (OCC); 12 CFR 217.12(c) (Board); 12 CFR 324.12(c) (FDIC) (community bank leverage ratio framework); 12 CFR 235.5(a)(3) (rules regarding debit card interchange fees and routing).

assuming that the organization remains above the relevant threshold.

The agencies have determined not to amend in this interim final rule a provision in the agencies' regulations regarding section 13 of the Bank Holding Company Act (BHC Act) (commonly known as the Volcker Rule). The Volcker Rule generally applies to ''banking entities,'' which include insured depository institutions, their affiliates, and any company that controls an insured depository institution, among other companies.[17] For purposes of the Volcker Rule, the definition of ''insured depository institution'' excludes an insured depository institution if the insured depository institution, and every entity that controls it, has total consolidated assets equal to or less than $10 billion, as long as the total consolidated trading assets and liabilities of the insured depository institution, and every entity that controls it, are equal to or less than five percent of the insured depository institution's total consolidated assets.[18]

The agencies have determined that it is not necessary to amend the Volcker Rule regulations in order to provide temporary regulatory burden relief to a bank or any of its subsidiaries or affiliates that become a ''banking entity'' for purposes of the Volcker Rule because the assets of the bank or any entity that controls it increase above the $10 billion asset threshold. Under section 13 of the BHC Act and the Board's rule implementing the conformance period in the Volcker Rule,[19] an entity that newly becomes a ''banking entity'' for purposes of the Volcker Rule has two years to come into compliance with the requirements of the Volcker Rule, and may seek an extension of the conformance period from the Board.[20] A banking entity that ceases to be a banking entity during that period—for example by virtue of reducing its asset size—would no longer be subject to the Volcker Rule.

The regulation implementing the statutory Volcker Rule conformance period have not yet been updated to account for the change in the definition of ''banking entity'' implemented by EGRRCPA. However, the Board notes that because the changes EGRRCPA made to the Volcker Rule were effective immediately upon enactment, the conformance period regulation should be read in a way that is consistent with EGRRCPA and takes into account the amendments it made to the definition of ''banking entity.'' Under this interpretation, a company may become a new banking entity by virtue of crossing the $10 billion asset threshold under the definition of ''banking entity,'' as amended by EGRRCPA. Therefore, for the sake of clarification, the Board confirms that a company that was not a banking entity, or a subsidiary or affiliate of a banking entity, and then becomes a banking entity for purposes of the Volcker Rule because it, or any subsidiary or affiliate, exceeds $10 billion in assets, will qualify for the conformance period described in the Volcker Rule and the Board's implementing regulations.[21] This interpretation covers any company that crossed the $10 billion asset threshold after the enactment of EGRRCPA on May 24, 2018, including a company that crossed the threshold after December 31, 2019.

A. Reservation of Authority

The temporary regulatory burden relief described above is generally available to community banking organizations that meet the requirements described above. However, there may be limited instances in which such regulatory burden relief would be inappropriate. In order to address certain such situations, the agencies may use existing reservations of authority in their respective regulations to require a community banking organization to comply with a given regulatory requirement that would otherwise not be applicable to the organization pursuant to the relief provided by this interim final rule. Additionally, with respect to each of the asset-based regulatory thresholds that did not previously include a reservation of authority, the interim final rule creates a new reservation of authority pursuant to which an agency may determine that a community banking organization is not eligible to use the relief provision with respect to one or more of the asset thresholds covered by the rule if the relevant agency makes an institution-specific determination that permitting the institution to determine its assets in accordance with that relief provision would not be appropriate based on the organization's risk profile.[22] [23] When making any such determination, the agencies would consider all relevant factors, including the extent of asset growth of the community banking organization since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the community banking organization has become involved in any additional activities since December 31, 2019, and, if so, the risk of such activities; the asset size of any parent companies; and the type of assets held by the community banking organization.[24]

[17] 12 CFR 44.2(c) (OCC); 12 CFR 248.2(c) (Board); 12 CFR 324.12(c) (FDIC).

[18] 12 CFR 44.2(r) (OCC); 12 CFR 248.2(r)(2) (Board); 12 CFR 351.2(r)(2) (FDIC). The Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA), enacted on May 24, 2018, amended section 13 of the BHC Act by modifying the definition of ''banking entity,'' to exclude certain small firms from section 13's restrictions. EGRRCPA, Public Law 115–174, section 203 (May 24, 2018). This amendment was effective upon EGRRCPA's enactment.

[19] Pursuant to sections (c)(2) and (c)(6) of the Volcker Rule (12 U.S.C. 1851(c)(2) and (c)(6)), the Board has sole authority to issue rules to implement the Volcker Rule conformance period.

[20] *See* 12 CFR 225.181(a)(2), (3).

[21] Although the conformance regulation refers to a requirement that a company was not a banking entity as of July 21, 2010, EGRRCPA's change to the definition of ''banking entity'' means that a firm that was below the asset threshold as of July 21, 2010, regardless of whether it was subject to the Volcker Rule at the time, is eligible for the conformance period if it becomes a banking entity due to exceeding the asset threshold.

[22] With respect to the exemption for small issuers from the Board's rules regarding debit card interchange fees and routing, the reservation of authority will concern a determination related to the issuer's asset profile, rather than its risk profile, due to differences in the relevant statutory framework.

[23] The interim final rule does not include a new reservation of authority in connection with the temporary relief provided with respect to the $3 billion threshold in the agencies' rules that determines, in part, a depository institution's eligibility for an 18-month examination cycle, because the rules already contain a reservation of authority pursuant to which each agency may examine any depository institution that it supervises as frequently as the agency deems necessary. 12 CFR 4.6(c) and 4.7(c) (OCC); 12 CFR 208.64(c) (Board); 12 CFR 337.12(c) and 12 CFR 347.211(c) (FDIC). Amendments to the agencies' capital regulations governing eligibility for use of the community bank leverage ratio framework and regulations affecting the prohibition on certain management official interlocks each include a reservation of authority. The agencies may exercise this reservation of authority to determine that such relief provisions shall not apply to a supervised institution if the relevant agency determines that such relief would not be commensurate with the risk posed by the institution. Amendments to the regulations governing eligibility to use the FFIEC 051 do not include new reservations of authority because the existing reservations of authority would continue to apply. The existing Call Reports rules reserve the authority of each agency to require a depository intuition otherwise eligible for reduced reporting to file the FFIEC 041 version of the report of condition. 12 CFR 52.4 (OCC); 12 CFR 304.14 (FDIC).

[24] The temporary regulatory burden relief provided by this interim final rule does not eliminate any existing authority of the Board to apply a regulatory standard, such as a standard related to application processing, to a community banking organization that, due to its asset size, would otherwise not qualify for the standard. For example, a bank holding company that meets certain characteristics, including asset-size limits, may be eligible for streamlined application processing. However, the Board or its delegatee may in its discretion notify such organizations that a full application is required in order to permit a closer

In particular, in determining that the community banking organization is not eligible to use a regulatory burden relief provision, the relevant agency will consider whether a community banking organization crossed an asset-based regulatory threshold due to a merger or acquisition that significantly increases the community banking organization's asset size. Asset growth that occurs as a result of a merger or acquisition is planned, unlike the growth that many community banking organizations have experienced since the beginning of the COVID event. Community banking organizations crossing a regulatory threshold as a result of a merger or acquisition therefore have had the opportunity to prepare for the change in regulatory requirements. Additionally, asset growth caused by a merger or acquisition is generally expected to be permanent and therefore not impose transition costs for a requirement expected to be temporary. The reservations of authority included in this interim final rule are not limited to situations in which there has been a merger or acquisition because, even in the absence of a merger or acquisition transaction, significant asset growth at a community banking organization may reflect a material change in the business model, risk profile, or complexity of the community banking organization. Nonetheless, the agencies expect to apply the reservation of authority only in limited circumstances, such as when there is significant growth due to a merger or acquisition or when there is a material change in the business model, risk profile, or complexity of the community banking organization.

B. Regulatory Reporting Changes

Similar to the Board's regulations, a number of the Board's regulatory reports contain asset-based thresholds that determine whether a banking organization is required to report certain information. For the same reason that the Board is providing the regulatory burden relief discussed above with regard to determining the applicability of asset-based thresholds contained in the Board's regulations, the Board is temporarily revising certain of its regulatory reports that contain asset-based reporting thresholds set at $10 billion or less pursuant to the Board's authority to temporarily revise a collection of information without providing the opportunity for public comment. This regulatory burden relief applies to reports with as-of dates up to and including December 31, 2021. Specifically, with regard to each of the regulatory reports discussed below, through December 31, 2021, a banking organization will be permitted to determine the applicability of asset-based reporting thresholds set at $10 billion or less using asset data as of December 31, 2019, if the organization's assets as of that date were less than its assets on the date as of which the applicability of a given threshold would normally be determined. The revisions to the affected reports do not affect the substantive reporting instructions for any item, schedule, or report. Rather, they merely affect which banking organizations are required to report certain items, schedules, or reports.

As with regard to asset-based regulatory thresholds, and for the same reasons, the Board will retain a reservation of authority with regard to each of the affected reports, pursuant to which the Board would retain the authority to require a banking organization to use an asset measurement date other than December 31, 2019, to determine compliance with a reporting threshold. The Board will use the same factors in determining whether to exercise its reservation of authority with regard to reporting thresholds as with regard to regulatory thresholds.

The regulatory burden relief discussed above applies to the following information collections:

- Financial Statements for Holding Companies (FR Y–9 Reports; OMB No. 7100–0128);
- Statements of U.S. Nonbank Subsidiaries of U.S. Holding Companies (FR Y–11 and FR Y–11S; 7100–0244);
- Reports of Foreign Banking Organizations (FR Y–7N, FR Y–7NS, and FR Y–7Q; 7100–0125); and
- Statements of Foreign Subsidiaries of U.S. Banks (FR 2314 and FR 2314S; OMB No. 7100–0073).

The agencies plan to publish a separate **Federal Register** notice that will address corresponding changes to the Call Reports.

The following chart summarizes the manner in which banking organizations will be required to determine the applicability of various reporting thresholds through the end of 2021 and afterwards.

TABLE 1—REPORTING REQUIREMENTS FOR AFFECTED FEDERAL RESERVE REPORTS UNDER THE INTERIM FINAL RULE AND AFTER REGULATORY BURDEN RELIEF ENDS [1]

Information collection	Reporting applicability for 2020–2021	Filers use assets as of these dates to determine reporting requirement for 2022 [2]
FR Y–9C (quarterly)—Consolidated Financial Statements for Holding Companies.	Report filing not required for holding company below the $3 billion asset threshold using the lesser of most current filing applicable date or 12/31/2019 as-of-date.	Use 06/30/2021 total assets to determine reporting applicability for reports with 2022 as-of dates.
FR Y–9LP (quarterly)—Parent Company Only Financial Statements for Large Holding Companies.	Report filing not required for holding company below the $3 billion asset threshold using the lesser of most current filing applicable date or 12/31/2019 as-of-date.	Use 06/30/2021 total assets to determine reporting applicability for reports with 2022 as-of dates.

review of the proposal. Nothing in this interim final rule affects the Board's authority to exercise such discretion, to request information that is needed to analyze the relevant statutory factors for an application or notice, or to consider the ability of a community banking organization that files a notice or application with the Board to comply with statutory or regulatory requirements that may be applicable to the organization upon expiration of the relief provided by this interim final rule.

Certain provisions of the Board's Regulation Y include asset-based thresholds of $10 billion or below that are based on the pro forma consolidated assets of a bank holding company or the consolidated risk-weighted assets of a bank holding company immediately following consummation of a proposed transaction. With regard to these thresholds, the interim final rule permits bank holding companies, through 2021, to calculate pro forma assets by adding together the assets that each company involved in a business combination had as of December 31, 2019. However, the calculation of pro forma or combined assets must also include the December 31, 2019, assets of any company with which any company that is party to a proposed business combination has itself combined with since December 31, 2019.

TABLE 1—REPORTING REQUIREMENTS FOR AFFECTED FEDERAL RESERVE REPORTS UNDER THE INTERIM FINAL RULE AND AFTER REGULATORY BURDEN RELIEF ENDS [1]—Continued

Information collection	Reporting applicability for 2020–2021	Filers use assets as of these dates to determine reporting requirement for 2022 [2]
FR Y–11 (quarterly)—Financial Statements of U.S. Nonbank Subsidiaries of U.S. Bank Holding Companies.	Quarterly report filing not required if nonbank subsidiary had assets of at least $500 million but less than $1 billion using the lesser of most current filing applicable date or 12/31/2019 as-of-date and does not meet any the other criteria to file quarterly.	Use 06/30/2021 total assets to determine eligibility for reports with 2022 as-of dates.
FR Y–11 (annual)—Financial Statements of U.S. Nonbank Subsidiaries of U.S. Bank Holding Companies.	Annual report filing not required if nonbank subsidiary has assets of less than $500 million using the lesser of most current filing applicable date or 12/31/2019 as-of-date.	Use total assets as of the reporting as-of date (12/31/2022) to determine reporting applicability.
FR Y–11S (annual)—Abbreviated Financial Statements of U.S. Nonbank Subsidiaries of U.S. Holding Co.	Report filing not required if nonbank subsidiary was not greater than $250 million and less than $500 million using the lesser of most current filing applicable date or 12/31/2019 as-of-date and does not meet the other filing criteria.	Use total assets as of the reporting as-of date (12/31/2022) to determine reporting applicability.
FR Y–7N (quarterly)—Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations.	Quarterly report filing not required if nonbank subsidiary was below the $1 billion asset threshold using the lesser of most current filing applicable date or 12/31/2019 as-of-date and does not meet any other filing criteria.	Use total assets as of the reporting as-of date to determine reporting applicability.
FR Y–7N (annual)—Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations.	Report filing not required if nonbank subsidiary was not greater than $500 million and less than $1 billion using lesser of most current filing applicable date or 12/31/2019 as-of-date and does not meet any other filing criteria.	Use total assets as of the reporting as-of date (12/31/2022) to determine reporting applicability.
FR Y–7NS (annual)—Abbreviated Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations.	Report filing not required if nonbank subsidiary was not greater than $250 million and less than $500 million using the lesser of most current filing applicable date or 12/31/2019 as-of-date and does not meet the other filing criteria.	Use total assets as of the reporting as-of date (12/31/2022) to determine reporting applicability.
FR 2314 (quarterly)—Financial Statements of Foreign Subsidiaries of U.S. Banking Organizations.	Quarterly report filing not required if nonbank subsidiary has assets less than $1 billion using the lesser of most current filing applicable date or 12/31/2019 as-of-date and does not meet any of other criteria to file quarterly.	Use 06/30/2021 total assets to determine eligibility for reports with 2022 as-of dates.
FR 2314 (annual)—Financial Statements of Foreign Subsidiaries of U.S. Banking Organizations.	Report filing not required if nonbank was not greater than $500 million and less than $1 billion in total assets using lesser of most current filing applicable date or 12/31/2019 as-of-date.	Use total assets as of the reporting as-of date (12/31/2022) to determine reporting applicability.
FR 2314S (annual)—Abbreviated Financial Statements of Foreign Subsidiaries of U.S. Banking Org.	Report filing not required if nonbank was not greater than $250 million and less than $500 million in total asset using the lesser of most current filing applicable date or 12/31/2019 as-of-date.	Use total assets as of the reporting as-of date (12/31/2022) to determine reporting applicability.

[1] During 2020–2021, applicability of new reporting requirements would be based on the December 31, 2019 data. For example, a holding company that does not currently file the FR Y–9C will not use its June 2020 total consolidated assets (TCA) to determine the March 31, 2021, filing requirement, and would not be required to file the FR Y–9C report until March 21, 2022. After the regulatory burden relief ends, the institution would use June 30, 2021, TCA to determine initial filing for the March 31, 2022, reporting period.

[2] Beginning January 1, 2022, asset measurement for applicability of reporting will revert-back to how institutions determined applicability prior to the reporting relief.

II. Request for Comment

The agencies seek comment on all aspects of this interim final rule. In particular, the agencies seek comment on the duration of the temporary regulatory burden relief and on the following specific question:

(1): What are the advantages and disadvantages of requiring community banking organizations subject to this interim final rule to determine compliance with regulatory thresholds using the lesser of an organization's assets as of December 31, 2019, and its assets on the date as of which the applicability of a given threshold would normally be determined? What would be the advantages and disadvantages of an alternative measurement date? Commenters are invited to describe other dates and the advantages and disadvantages of any such dates.

III. Administrative Law Matters

A. Administrative Procedure Act

The agencies are issuing the interim final rule without prior notice and the opportunity for public comment and without the 30-day delayed effective date ordinarily prescribed by the

Administrative Procedure Act (APA).[25] Pursuant to section 553(b)(B) of the APA, general notice and the opportunity for public comment are not required with respect to a rulemaking when an ''agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' [26]

As discussed above, the interim final rule provides temporary regulatory burden relief to community banking organizations crossing regulatory and reporting asset thresholds in 2020 and 2021. Many community banking organizations have experienced dramatic and unexpected increases in their assets as a result of their efforts to support the economy during the ongoing COVID event. As noted, a significant portion of this asset growth can be traced to participation by community banking organizations in emergency lending programs sponsored by the U.S. government, other lending related to the COVID event, and an unexpected surge in deposits. The interim final rule facilitates the ability of community banking organizations to temporarily defer the implementation of regulatory and reporting thresholds that would not have been applicable had they not experienced this growth in assets. Therefore, the interim final rule benefits community banking organizations from the above referenced regulations and reports by providing temporary regulatory burden relief. The interim final rule does not impose any requirements on any covered community banking organizations.

The agencies believe that the public interest is best served by making the interim final rule effective immediately upon publication in the **Federal Register**. The agencies believe that issuing the interim final rule will ensure that community banking organizations will not be unnecessarily required to comply with threshold-based regulatory standards that may not be appropriate given the organizations' likely long-term risk profile and activities after the reversal of any temporary growth. The interim final rule also will allow community banking organizations to avoid the costs of temporarily complying with regulatory requirements, allowing the banking organizations to continue to focus on the provision of credit during this time of economic stress. In addition, the agencies believe that providing a notice and comment period prior to issuance of the interim final rule is impracticable, as community banking organizations may start incurring transition costs prior to the end of 2020 in anticipation of needing to comply with additional requirements starting as early as December 31, 2020. For these reasons, the agencies find there is good cause consistent with the public interest to issue the interim final rule without advance notice and comment.

The APA also requires a 30-day delayed effective date, except for (1) substantive rules which grant or recognize an exemption or relieve a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause.[27] The agencies find good cause to publish the interim final rule with an immediate effective date for the same reasons set forth above under the discussion of section 553(b)(B) of the APA.

While the agencies believe there is good cause to issue the interim final rule without advance notice and comment and with an immediate effective date, the agencies are requesting comment on all aspects of the interim final rule.

B. Congressional Review Act

For purposes of Congressional Review Act (CRA), OMB makes a determination as to whether a final rule constitutes a ''major'' rule.[28] If a rule is deemed a ''major rule'' by the OMB, the CRA generally provides that the rule may not take effect until at least 60 days following its publication.[29]

The CRA defines a ''major rule'' as any rule that the Administrator of the Office of Information and Regulatory Affairs of the OMB finds has resulted in or is likely to result in (1) an annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions, or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.[30]

For the same reasons set forth above, the agencies are adopting the interim final rule without the delayed effective date generally prescribed under the CRA. The delayed effective date required by the CRA does not apply to any rule for which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. In light of current market uncertainty and because community banking organizations may start incurring transition costs prior to the end of 2020 in anticipation of needing to comply with additional requirements starting as early as December 31, 2020, the agencies believe that delaying the effective date of the rule would be contrary to the public interest.

As required by the CRA, the agencies will submit the final rule and other appropriate reports to Congress and the Government Accountability Office for review.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) states that no agency may conduct or sponsor, nor is a respondent required to respond to, an information collection unless it displays a currently valid OMB control number.[31] The interim final rule affects the agencies' current information collections for the Call Reports (FFIEC 031, FFIEC 041, and FFIEC 051). The OMB control numbers for the Call Reports of the agencies are: OCC OMB No. 1557–0081; Board OMB No. 7100–0036; and FDIC OMB No. 3064–0052.

For purposes of the Call Reports, any change resulting from the relief provided by this interim final rule should be minimal and result in a zero net change in hourly burden under the agencies' information collections. Submissions will, however, be made by the agencies to OMB. The changes to the instructions of the Call Reports will be addressed in a separate **Federal Register** notice.

In addition, this interim final rule does not introduce any new information collections. It does, however, temporarily impact the following information collections: FR Y–9 Reports; FR Y–11; FR Y–11S; FR Y–7N; FR Y–7NS; FR 2314; and FR 2314S. The Board has reviewed this interim final rule pursuant to authority delegated by the OMB. The Board has temporarily revised the instructions for these information collections to reflect changes made in the interim final rule.

On June 15, 1984, OMB delegated to the Board authority under the PRA to approve a temporary revision to a collection of information without

[25] 5 U.S.C. 553.

[26] 5 U.S.C. 553(b)(B).

[27] 5 U.S.C. 553(d).

[28] 5 U.S.C. 801 *et seq.*

[29] 5 U.S.C. 801(a)(3).

[30] 5 U.S.C. 804(2).

[31] 44 U.S.C. 3501–3521.

providing opportunity for public comment if the Board determines that a change in an existing collection must be instituted quickly and that public participation in the approval process would defeat the purpose of the collection or substantially interfere with the Board's ability to perform its statutory obligation.

The Board's delegated authority requires that the Board, after temporarily approving a collection, solicit public comment on a proposal to extend the temporary collection for a period not to exceed three years. Therefore, the Board is inviting comment on a proposal to extend these information collections for three years with such revisions. The Board invites public comment on the information collections, which are being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the collections of information are necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collections, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Comments must be submitted on or before February 1, 2021. At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the information collection.

Approval Under OMB Delegated Authority of the Temporary Revision of, and Proposal To Extend for Three Years, With Revision, the Following Information Collections

1. Report Title: Financial Statements for Holding Companies

Agency form number: FR Y–9C, FR Y–9LP, FR Y–9SP, FR Y–9ES, and FR Y–9CS.

OMB control number: 7100–0128.

Effective date: December 2, 2020.

Frequency: Quarterly, semiannually, and annually.

Respondents: Bank holding companies, savings and loan holding companies, securities holding companies, and U.S. intermediate holding companies (collectively, holding companies).

Estimated number of respondents: FR Y–9C (non-advanced approaches community bank leverage ratio holding companies with less than $5 billion in total assets): 71; FR Y–9C (non-advanced approaches community bank leverage ratio holding companies with $5 billion or more in total assets): 35; FR Y–9C (non-advanced approaches, non-community bank leverage ratio, holding companies with less than $5 billion in total assets): 84; FR Y–9C (non-advanced approaches, non-community bank leverage ratio holding companies, with $5 billion or more in total assets): 154; FR Y–9C (advanced approaches holding companies): 19; FR Y–9LP: 434; FR Y–9SP: 3,960; FR Y–9ES: 83; FR Y–9CS: 236.

Estimated annual burden hours:

Reporting

FR Y–9C (non-advanced approaches community bank leverage ratio holding companies with less than $5 billion in total assets): 8,284 hours; FR Y–9C (non-advanced approaches community bank leverage ratio holding companies with $5 billion or more in total assets): 4,920; FR Y–9C (non-advanced approaches non community bank leverage ratio holding companies with less than $5 billion in total assets): 13,779; FR Y–9C (non-advanced approaches non-community bank leverage ratio holding companies with $5 billion or more in total assets): 28,940 hours; FR Y–9C (advanced approaches holding companies): 3,747 hours; FR Y–9LP: 9,149 hours; FR Y–9SP: 42,768 hours; FR Y–9ES: 42 hours; FR Y–9CS: 472 hours.

Recordkeeping

FR Y–9C (non-advanced approaches holding companies with less than $5 billion in total assets): 620 hours; FR Y–9C (non-advanced approaches holding companies with $5 billion or more in total assets): 756 hours; FR Y–9C (advanced approaches holding companies): 76 hours; FR Y–9LP: 1,736 hours; FR Y–9SP: 3,960 hours; FR Y–9ES: 42 hours; FR Y–9CS: 472 hours.

General description of report: The FR Y–9 family of reporting forms continues to be the primary source of financial data on holding companies that examiners rely on in the intervals between on-site inspections. Financial data from these reporting forms are used to detect emerging financial problems, to review performance and conduct pre-inspection analysis, to monitor and evaluate capital adequacy, to evaluate holding company mergers and acquisitions, and to analyze a holding company's overall financial condition to ensure the safety and soundness of its operations. The FR Y–9C, FR Y–9LP, and FR Y–9SP serve as standardized financial statements for the consolidated holding company. The Board requires holding companies to provide standardized financial statements to fulfill the Board's statutory obligation to supervise these organizations. The FR Y–9ES is a financial statement for holding companies that are Employee Stock Ownership Plans. The Board uses the voluntary FR Y–9CS (a free-form supplement) to collect additional information deemed to be critical and needed in an expedited manner. Holding companies file the FR Y–9C quarterly, the FR Y–9LP quarterly, the FR Y–9SP semiannually, the FR Y–9ES annually, and the FR Y–9CS on a schedule that is determined when this supplement is used.

Legal authorization and confidentiality: The Board has the authority to impose the reporting and recordkeeping requirements associated with the FR Y–9 family of reports on bank holding companies pursuant to section 5 of the BHC Act, (12 U.S.C. 1844); on savings and loan holding companies pursuant to section 10(b)(2) and (3) of the Home Owners' Loan Act, (12 U.S.C. 1467a(b)(2) and (3)); on U.S. intermediate holding companies pursuant to section 5 of the BHC Act, (12 U.S.C 1844), as well as pursuant to sections 102(a)(1) and 165 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), (12 U.S.C. 511(a)(1) and 5365); and on securities holding companies pursuant to section 618 of the Dodd-Frank Act, (12 U.S.C. 1850a(c)(1)(A)). The FR Y–9 series of reports, and the recordkeeping requirements set forth in the respective instructions to each report, are mandatory, except for the FR Y–9CS, which is voluntary.

With respect to the FR Y–9C, Schedule HI Memoranda item 7.g, Schedule HC–P item 7.a, and Schedule HC–P item 7.b are considered confidential commercial and financial information under exemption 4 of the Freedom of Information Act (FOIA), (5 U.S.C. 552(b)(4)), as is Schedule HC Memoranda item 2.b for both the FR Y–9C and FR Y–9SP reports. Such treatment is appropriate under exemption 4 of the FOIA (5 U.S.C. 552(b)(4)) because these data items reflect commercial and financial information that is both customarily and actually treated as private by the

submitter, and which the Board has previously assured submitters will be treated as confidential. It also appears that disclosing these data items may reveal confidential examination and supervisory information, and in such instances, this information would also be withheld pursuant to exemption 8 of the FOIA (5 U.S.C. 552(b)(8)), which protects information related to the supervision or examination of a regulated financial institution.

In addition, for both the FR Y–9C report and the FR Y–9SP report, Schedule HC Memoranda item 2.b, the name and email address of the external auditing firm's engagement partner, is considered confidential commercial information and protected by exemption 4 of the FOIA (5 U.S.C. 552(b)(4)) if the identity of the engagement partner is treated as private information by holding companies. The Board has assured respondents that this information will be treated as confidential since the collection of this data item was proposed in 2004.

Additionally, items on the FR Y–9C, Schedule HC–C regarding loans modified under Section 4013 (Memoranda item 16.a, ''Number of Section 4013 loans outstanding'', and Memoranda item 16.b, ''Outstanding balance of Section 4013 loans'') are considered confidential. While the Board generally makes institution-level FR Y–9C report data publicly available, the Board believes the disclosure of these items at the holding company level would not be in the public interest.[32] Such information is permitted to be collected on a confidential basis, consistent with 5 U.S.C. 552(b)(8).[33] Holding companies may be reluctant to offer modifications under Section 4013 if information on these modifications is publicly available, as analysts, investors, and other users of public FR Y–9C report information may penalize an institution for using the relief provided by the CARES Act.

Aside from the data items described above, the remaining data items on the FR Y–9 report and the FR Y–9SP report are generally not accorded confidential treatment. The data items collected on FR Y–9LP, FR Y–9ES, and FR Y–9CS reports, are also generally not accorded confidential treatment. As provided in the Board's Rules Regarding Availability of Information (12 CFR part 261), however, a respondent may request confidential treatment for any data items the respondent believes should be withheld pursuant to a FOIA exemption. The Board will review any such request to determine if confidential treatment is appropriate, and will inform the respondent if the request for confidential treatment has been denied.

To the extent that the instructions to the FR Y–9C, FR Y–9LP, FR Y–9SP, and FR Y–9ES reports each respectively direct a financial institution to retain the workpapers and related materials used in preparation of each report, such material would only be obtained by the Board as part of the examination or supervision of the financial institution. Accordingly, such information may be considered confidential pursuant to exemption 8 of the FOIA (5 U.S.C. 552(b)(8)). In addition, the financial institution's workpapers and related materials may also be protected by exemption 4 of the FOIA, to the extent such financial information is treated as confidential by the respondent (5 U.S.C. 552(b)(4)).

2. *Report Title:* Financial Statements of U.S. Nonbank Subsidiaries of U.S. Holding Companies and Abbreviated Financial Statements of U.S Nonbank Subsidiaries of U.S. Holding Companies

Agency form number: FR Y–11 and FR Y–11S.

OMB control number: 7100–0244.

Effective date: December 2, 2020.

Frequency: Quarterly and annually.

Respondents: Domestic bank holding companies, savings and loan holding companies, securities holding companies, and intermediate holding companies.

Estimated number of respondents: FR Y–11 (quarterly): 445; FR Y–11 (annually): 189; FR Y–11S: 273.

Estimated annual burden hours: FR Y–11 (quarterly): 13,528 hours; FR Y–11 (annually): 1,436 hours; FR Y–11S: 273 hours.

General description of report: The FR Y–11 family of reports collects financial information for individual U.S. nonbank subsidiaries of domestic holding companies, which is essential for monitoring the subsidiaries' potential impact on the condition of the holding company or its subsidiary banks. Holding companies file the FR Y–11 on a quarterly or annual basis or the FR Y–11S on an annual basis, predominantly based on whether the organization meets certain asset size thresholds.

Legal authorization and confidentiality: The Board has the authority to require bank holding companies and any subsidiary thereof, savings and loan holding companies and any subsidiary thereof, and securities holding companies and any affiliate thereof to file the FR Y–11 pursuant to, respectively, section 5(c) of the BHC Act (12 U.S.C. 1844(c)), section 10(b) of the Homeowners' Loan Act (12 U.S.C. 1467a(b)), and section 618 of the Dodd-Frank Act (12 U.S.C. 1850a).

Information collected in these reports generally is not considered confidential. However, because the information is collected as part of the Board's supervisory process, certain information may be afforded confidential treatment pursuant to exemption 8 of the FOIA (5 U.S.C. 552(b)(8)). Individual respondents may request that certain data be afforded confidential treatment pursuant to exemption 4 of the FOIA if the data has not previously been publically disclosed and the release of the data would likely cause substantial harm to the competitive position of the respondent (5 U.S.C. 552(b)(4)). Additionally, individual respondents may request that personally identifiable information be afforded confidential treatment pursuant to exemption 6 of the FOIA if the release of the information would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552(b)(6)). The applicability of the FOIA exemptions 4 and 6 would be determined on a case-by-case basis.

3. *Report Title:* The Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations, Abbreviated Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations, and the Capital and Asset Report of Foreign Banking Organizations

Agency form number: FR Y–7N, FR Y–7NS, and FR Y–7Q.

OMB control number: 7100–0125.

Effective date: December 2, 2020.

Frequency: Quarterly and annually.

Respondents: Foreign banking organizations.

Estimated number of respondents: FR Y–7N (quarterly): 35; FR Y–7N (annually): 19; FR Y–7NS: 22; FR Y–7Q (quarterly): 130; FR Y–7Q (annually): 29.

Estimated annual burden hours: FR Y–7N (quarterly): 1,064 hours; FR Y–7N (annually): 144 hours; FR Y–7NS: 22 hours; FR Y–7Q (quarterly): 1,560 hours; FR Y–7Q (annually): 44 hours.

General description of report: The FR Y–7N and the FR Y–7NS are used to assess a foreign banking organization's ability to be a continuing source of strength to its U.S. nonbank operations and to determine compliance with U.S.

[32] See 12 U.S.C. 1464(v)(2).

[33] Exemption 8 of the Freedom of Information Act (FOIA) specifically exempts from disclosure information ''contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions.''

laws and regulations. Foreign banking organizations file the FR Y–7N quarterly or annually, or the FR Y–7NS annually, predominantly based on asset size thresholds. The FR Y–7Q is used to assess consolidated regulatory capital and asset information from all foreign banking organizations. The FR Y–7Q is filed quarterly by foreign banking organizations that have effectively elected to become or be treated as a U.S. financial holding company and by foreign banking organizations that have total consolidated assets of $50 billion or more, regardless of financial holding company status. All other foreign banking organizations file the FR Y–7Q annually.

Legal authorization and confidentiality: With respect to foreign banking organizations and their subsidiary intermediate holding companies, section 5(c) of the BHC Act, in conjunction with section 8 of the International Banking Act (12 U.S.C. 3106), authorizes the board to require foreign banking organizations and any subsidiary thereof to file the FR Y–7N reports, and the FR Y–7Q. Information collected in these reports generally is not considered confidential. However, because the information is collected as part of the Board's supervisory process, certain information may be afforded confidential treatment pursuant to exemption 8 of the FOIA (5 U.S.C. 552(b)(8)). Individual respondents may request that certain data be afforded confidential treatment pursuant to exemption 4 of the FOIA if the data has not previously been publicly disclosed and the release of the data would likely cause substantial harm to the competitive position of the respondent (5 U.S.C. 552(b)(4)). Additionally, individual respondents may request that personally identifiable information be afforded confidential treatment pursuant to exemption 6 of the FOIA if the release of the information would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552(b)(6)). The applicability of the FOIA exemptions 4 and 6 would be determined on a case-by-case basis.

4. *Report Title:* Financial Statements of Foreign Subsidiaries of U.S. Banking Organizations and the Abbreviated Financial Statements of Foreign Subsidiaries of U.S. Banking Organizations

Agency form number: FR 2314 and FR 2314S.

OMB control number: 7100–0073.

Effective date: December 2, 2020.

Frequency: Quarterly and annually.

Respondents: U.S. state member banks, bank holding companies, savings and loan holding companies, intermediate holding companies, and Edge or agreement corporations.

Estimated number of respondents: FR 2314 (quarterly): 439; FR 2314 (annually): 239; FR 2314S: 300.

Estimated annual burden hours: FR 2314 (quarterly): 12,643 hours; FR 2314 (annually): 1,768 hours; FR 2314S: 300 hours.

General description of report: The FR 2314 family of reports is the only source of comprehensive and systematic data on the assets, liabilities, and earnings of the foreign nonbank subsidiaries of U.S. banking organizations, and the data are used to monitor the growth, profitability, and activities of these foreign companies. The data help the Board identify present and potential problems of these companies, monitor their activities in specific countries, and develop a better understanding of activities within the industry and within specific institutions. Parent organizations (state member banks, Edge and agreement corporations, or holding companies) file the FR 2314 on a quarterly or annual basis, or the FR 2314S on an annual basis, predominantly based on whether the organization meets certain asset size thresholds.

Legal authorization and confidentiality: The Board has the authority to require bank holding companies and any subsidiary thereof, savings and loan holding companies and any subsidiary thereof, and securities holding companies and any affiliate thereof to file the FR 2314 pursuant to, respectively, section 5(c) of the BHC Act (12 U.S.C. 1844(c)), section 10(b) of the Homeowners' Loan Act (12 U.S.C. 1467a(b)), and section 618 of the Dodd-Frank Act (12 U.S.C. 1850a). The Board has the authority to require state member banks, agreement corporations, and Edge corporations to file the FR 2314 pursuant to, respectively, sections 9(6), 25(7), and 25A(17) of the Federal Reserve Act (12 U.S.C. 324, 602, and 625). With respect to foreign banking organizations and their subsidiary intermediate holding companies, section 5(c) of the BHC Act, in conjunction with section 8 of the International Banking Act (12 U.S.C. 3106), authorizes the board to require foreign banking organizations and any subsidiary thereof to file the FR 2314 reports. These reports are mandatory.

Information collected in these reports generally is not considered confidential. However, because the information is collected as part of the Board's supervisory process, certain information may be afforded confidential treatment pursuant to exemption 8 of the FOIA (5 U.S.C. 552(b)(8)). Individual respondents may request that certain data be afforded confidential treatment pursuant to exemption 4 of the FOIA if the data has not previously been publically disclosed and the release of the data would likely cause substantial harm to the competitive position of the respondent (5 U.S.C. 552(b)(4)). Additionally, individual respondents may request that personally identifiable information be afforded confidential treatment pursuant to exemption 6 of the FOIA if the release of the information would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552(b)(6)). The applicability of the FOIA exemptions 4 and 6 would be determined on a case-by-case basis.

Current actions: The interim final rule adjusts for community banking organizations the measurement dates for certain total asset thresholds that would otherwise trigger additional information collection requirements for the remainder of calendar years 2020 through the end of 2021. The temporary relief applies only to filing requirements associated with asset-based reporting thresholds of $10 billion or less. Table 1 of the interim final rule contains a summary of affected reports, reporting applicability for 2020–2021, and the dates for determining reporting requirements for 2022.

To implement the interim final rule, the Board is temporarily revising the instructions for the following reports: FR Y–9C, FR Y–9LP, FR Y–11, FR Y–11S, FR Y–7N, FR Y–7NS, FR 2314, and FR 2314S. The revised instructions instruct community banking organizations to use the lesser of total assets as of December 31, 2019, or the most recent applicable measurement period to determine the applicability of asset-based filing thresholds for the remainder of calendar years 2020 through the end of 2021. All reporting eligibility criteria for these information collections, besides the temporarily revised total assets measurement date, continue to apply. Financial institutions must revert back to normal rules for determining applicability of the reporting requirements in calendar year 2022, as summarized in Table 1.

The Board believes the changes to the measurement dates for the total asset thresholds used to determine additional reporting requirements will not result in a change in the burden estimates currently approved by OMB. Therefore, the burden estimates for these reports remain unchanged by the interim final rule.

The FR Y–9C instructions currently contain filing thresholds of $5 billion

and $10 billion that trigger the reporting of additional schedules and the reporting of certain data items at a higher frequently. These thresholds would be impacted by the changes in the interim final rule. Whether additional FR Y–9C requirements apply would normally be based on total consolidated assets as of June 30 of the prior year. With the revisions in the interim final rule, community banking organizations may instead use the lesser of total consolidated assets as of December 31, 2019, or June 30, 2020, to determine whether additional filing requirements are applicable.

Specifically, the additional filing requirements for the FR Y–9C that would otherwise be triggered by the $5 billion and $10 billion threshold are as follows:

• The $5 billion threshold requires these holding companies to report Schedule HI–C, Part I, Disaggregated Data on the Allowance for Loan and Lease Losses; Schedule HC–D, Trading Assets and Liabilities; Schedule HC–P, 1–4 Family Residential Mortgage Banking Activities in Domestic Offices; Schedule HC–Q, Assets and Liabilities Measured at Fair Value; Schedule HC–S, Servicing, Securitization, and Asset Sale Activities; and Schedule HC–V, Variable Interest Entities.

• The $5 billion threshold requires these holding companies to report Schedule HI item 1.e, interest income from trading assets; Schedule HI item 2.c, interest on trading liabilities and other borrowed money; Schedule HI item 2.d, interest on subordinated notes and debentures and on mandatory convertible securities; Schedule HI item 5.c, trading revenue; Schedule HI items 5.d.(1) through 5.d.(5), related to various fees and commissions on securities brokerage investments, investment banking, and insurance; Schedule HI item 5.e, venture capital revenue; Schedule HI item 5.g, net securitization income; Schedule HI Memoranda item 1, net interest income on a fully taxable equivalent basis; Schedule HI Memoranda item 2, net income before applicable income taxes, and discontinued operations; Schedule HI Memoranda items 8.a.(1) through 8.b.(2), discontinued operations and applicable income tax effect; Schedule HI Memoranda items 9.a through 9.e, related to trading revenue; Schedule HI Memoranda item 11, credit losses on derivatives; Schedule HI Memoranda items 12.a through 12.c, detail pertaining to income from the sale and servicing of mutual funds and annuities (in domestic offices); Schedule HI Memoranda items 14.a. through 14.b.(1), related to net gains (losses) recognized in earnings on assets and liabilities that are reported at fair value under a fair value option; Schedule HI Memoranda item 15, stock-based employee compensation expense; Schedule HI–B, Part I, items 4.a and 4.b, columns A and B, commercial and industrial loans; Schedule HI–B, Part I, item 6, columns A and B, loans to foreign governments and official institutions; Schedule HI–B, Part I, items 8.a and 8.b, lease finance receivables; Schedule HI–B, Part I, Memoranda item 2, columns A and B, loans secured by real estate to non-U.S. addressees; Schedule HI–B, Part I, Memoranda item 3, uncollectible retail credit card fees and finance charges reversed against income; Schedule HI–B, Part II, Memoranda item 1, allocated transfer risk reserve; Schedule HI–B, Part II, Memoranda item 2, separate valuation allowance for uncollectible retail credit card fees and finance charges; Schedule HI–B, Part II, Memoranda item 3, allowance for loan and lease losses attributable to retail credit card fees and finance charges; Schedule HI–B, Part II, Memoranda item 4, allowance for post-acquisition credit losses on purchased credit-impaired loans; Schedule HC–B, items 4.a.(1) through 4.a.(3), residential pass-through securities; Schedule HC–C, items 4.a and 4.b, commercial and industrial loans; Schedule HC–C, items 9.b.(1) through 9.b.(2), column A and B, loans for purchasing or carrying securities and all other loans; Schedule HC–C, items 10.a and 10.b, column A, lease financing receivables; Schedule HC–C Memoranda items 1.e.(1) and 1.e.(2), commercial and industrial loans; Schedule HC–C Memoranda item 3, loans secured by real estate to non-U.S. addressees; Schedule HC–C Memoranda item 4, outstanding credit card fees and finance charges; Schedule HC–C Memoranda items 12.a through 12.d, loans and leases held for investment (not subject to the requirements of FASB ASC 310–30) that are acquired in business combinations with acquisition dates in the current calendar year; Schedule HC–K, item 4.a, trading assets; Schedule HC–L item 1.b.(1), unused consumer credit card lines; Schedule HC–L 1.b.(2), other unused credit card lines; Schedule HC–L item 1.d, securities underwriting; Schedule HC–L items 2.a and 3.a, financial and performance standby letters of credit conveyed to others; Schedule HC–L items 7.a through 7.d.(2)(b), related to credit derivatives; Schedule HC–L items 11.a through 14.b.(2), pertaining to derivatives positions; Schedule HC–M items 6.a.(1)(a)(1) through 6.d, pertaining to assets covered by loss-sharing agreements with the Federal Deposit Insurance Corporation; Schedule HC–N, items 8.a and 8.b, columns A, B, and C; Schedule HC–N items 12.a.(1)(a) through 12.f, pertaining to loans and leases which are covered by loss-sharing agreements with the Federal Deposit Insurance Corporation; Schedule HC–N Memoranda items 1.e.(1) and 1.e.(2), columns A, B, and C, commercial and industrial loans; and Schedule HC–N Memoranda item 6, fair value of derivative contract amounts carried as assets.

• The $5 billion threshold requires these holding companies to report quarterly rather than annual Schedule HI Memoranda items 6.a through 6.j, other noninterest income; Schedule HI Memoranda items 7.a through 7.p, other noninterest expense; and Schedule HI Memoranda 16, noncash income from negative amortization on closed-end loans secured by 1–4 family residential properties; and quarterly rather than semi-annual, Schedule HI Memoranda item 17, other-than-temporary impairment losses on held-to-maturity and available-for-sale debt securities recognized in earnings; Schedule HI–C, Part II, items 7 through 11, disaggregated data on the allowance for credit losses; Schedule HC–C Memoranda items 1.a.(1) through 1.f.(3)(c), pertaining to loans restructured in troubled debt restructurings that are in compliance with their modified terms; Schedule HC–N Memoranda items 1.a.(1) through 1.d.(2) and 1.e.(3) through 1.f.(3)(c), related to loans restructured in troubled debt restructurings that are in compliance with their modified terms; Schedule HC–R, Part II, items 1 through 25, columns A through U, risk-weighted assets; Schedule HC–R, Part II Memoranda item 1, current credit exposure across all derivative contracts; Schedule HC–R, Part II Memoranda item 2, columns A, B, and C, notional principal amounts of over-the-counter derivative contracts; and Schedule HC–R, Part II, Memoranda item 3, columns A, B, and C, notional principal amounts of centrally cleared derivatives contracts.

• The $10 billion threshold requires these holding companies to report Schedule HI Memoranda items 10.a and 10.b, related to net gains/losses on credit derivatives; Schedule HC–B Memoranda items 5.a through 5.f, related to asset-backed securities; Schedule HC–B Memoranda items 6.a through 6.g, related to structured financial products by underlying collateral or reference assets; Schedule HC–L item 15, pertaining to the additional information on over-the-

counter derivatives; and Schedule HC–S items 6 and 10, and Schedule HC–S Memoranda item 3, related to securitization activity. Holding companies that cross the $10 billion threshold would be ineligible to opt-in into the community bank leverage ratio framework and would be required to file the additional Schedule HC–R, Part I and HC–R, Part II line items.

The Board has determined that the temporary revisions to these collections of information must be instituted quickly and that public participation in the approval process would defeat the purpose of the collections. Delaying the revisions would cause public harm if firms were adversely affected due to participating in the PPP or had to bear temporary compliance costs.

In addition, the Board proposes to extend the collections of information for three years with the revisions discussed above.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) [34] requires an agency to consider whether the rules it proposes will have a significant economic impact on a substantial number of small entities.[35] The RFA applies only to rules for which an agency publishes a general notice of proposed rulemaking pursuant to 5 U.S.C. 553(b). As discussed previously, consistent with section 553(b)(B) of the APA, the agencies have determined for good cause that general notice and opportunity for public comment is unnecessary, and therefore the agencies are not issuing a notice of proposed rulemaking. Accordingly, the agencies have concluded that the RFA's requirements relating to initial and final regulatory flexibility analysis do not apply.

Nevertheless, the agencies seek comment on whether, and the extent to which, the interim final rule would affect a significant number of small entities.

E. Riegle Community Development and Regulatory Improvement Act of 1994

Pursuant to section 302(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 (RCDRIA) [36] requires that each Federal banking agency, in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, each federal banking agency must consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations.

In addition, section 302(b) of RCDRIA requires new regulations and amendments to regulations that impose additional reporting, disclosures, or other new requirements on insured depository institutions generally to take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form.[37] The agencies have determined that the final rule would not impose additional reporting, disclosure, or other requirements; therefore, the requirements of the RCDRIA do not apply.

F. Unfunded Mandates Reform Act of 1995

As a general matter, the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531 *et seq.,* requires the preparation of a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. However, the UMRA does not apply to final rules for which a general notice of proposed rulemaking was not published. See 2 U.S.C. 1532(a). Therefore, because the OCC has found good cause to dispense with notice and comment for this interim final rule, the OCC has not prepared an economic analysis of the rule under the UMRA.

G. Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act [38] requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. In light of this requirement, the agencies have sought to present the interim final rule in a simple and straightforward manner and invite comment on the use of plain language. For example:

- *Is the material organized to suit your needs? If not, how could the agencies present the interim final rule more clearly?*
- *Are the requirements in the interim final rule clearly stated? If not, how could the interim final rule be more clearly stated?*
- *Does the interim final rule contain technical language or jargon that is not clear? If so, which language requires clarification?*
- *Would a different format (grouping and order of sections, use of headings, paragraphing) make the interim final rule easier to understand? If so, what changes would achieve that?*
- *Is this section format adequate? If not, which of the sections should be changed and how?*
- *What other changes can the agencies incorporate to make the interim final rule easier to understand?*

List of Subjects

12 CFR Part 3

Administrative practice and procedure, Capital, Federal savings associations, National banks, Risk.

12 CFR Part 4

Administrative practice and procedure, Freedom of information, Individuals with disabilities, Minority businesses, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Women.

12 CFR Part 52

Banks, Banking, Reporting and recordkeeping requirements.

12 CFR Part 208

Accounting, Agriculture Banks, Banking, Confidential business information, Consumer protection, Crime Currency, Federal Reserve System, Flood insurance, Insurance, Investments, Mortgages, Reporting and recordkeeping requirements, Securities.

12 CFR Part 211

Exports, Federal Reserve System, Foreign banking, Holding companies, Investments.

12 CFR Part 212

Antitrust, Banks, Banking, Holding companies.

12 CFR Part 217

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Holding companies, Investments, National banks, Reporting and recordkeeping requirements, Securities.

12 CFR Part 225

Administrative practice and procedure, Banks, Banking, Capital planning, Holding companies, Reporting and recordkeeping requirements, Securities, Stress testing.

[34] 5 U.S.C. 601 *et seq.*

[35] Under regulations issued by the Small Business Administration, a small entity includes a depository institution, bank holding company, or savings and loan holding company with total assets of $600 million or less and trust companies with total assets of $41.5 million or less. *See* 13 CFR 121.201.

[36] 12 U.S.C. 4802(a).

[37] 12 U.S.C. 4802.

[38] Public Law 106–102, 113 Stat. 1338, 1471, 12 U.S.C. 4809.

12 CFR Part 235

Accounting, Banks, Banking.

12 CFR Part 238

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Reporting and recordkeeping requirements, Securities.

12 CFR Part 304

Bank deposit insurance, Banks, Banking, Freedom of information, Reporting and recordkeeping requirements.

12 CFR Part 324

Administrative practice and procedure, Banks, Banking, Capital, Capital adequacy, Reporting and recordkeeping requirements, State non-member banks, Savings associations.

12 CFR Part 337

Banks, Banking, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 347

Authority delegations (Government agencies), Bank deposit insurance, Banks, Banking, Credit, Foreign banking, Investments, Reporting and recordkeeping requirements, U.S. investments abroad.

12 CFR Part 348

Antitrust, Banks, Banking, Holding companies, Savings associations.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Chapter I

Authority and Issuance

For the reasons stated in the joint preamble, the Office of the Comptroller of the Currency amends chapter I of Title 12 of the Code of Federal Regulations as follows:

PART 3—CAPITAL ADEQUACY STANDARDS

■ 1. The authority citation for part 3 continues to read as follows:

Authority: 12 U.S.C. 93a, 161, 1462, 1462a, 1463, 1464, 1818, 1828(n), 1828 note, 1831n note, 1835, 3907, 3909, 5412(b)(2)(B), and Pub. L. 116–136, 134 Stat. 281.

■ 2. Section 3.12 is amended by adding paragraph (a)(4) to read as follows:

§ 3.12 Community bank leverage ratio framework.

(a) * * *

(4)(i) *Temporary relief.* From December 2, 2020 through December 31, 2021, except as provided in paragraph (a)(4)(ii) of this section, the total consolidated assets of a national bank or Federal savings association for purposes of paragraph (a)(2)(ii) of this section shall be the lesser of:

(A) The total consolidated assets reported by the national bank or Federal savings association in its Call Report as of December 31, 2019; and

(B) The total consolidated assets of the national bank or Federal savings association calculated in accordance with the reporting instructions to the Call Report as of the end of the most recent calendar quarter.

(ii) *Reservation of authority.* The temporary relief provided under paragraph (a)(4)(i) of this section does not apply to a national bank or Federal savings association if the OCC determines that permitting the institution to determine its assets in accordance with that paragraph would not be commensurate with the risk posed by the institution. When making this determination, the OCC will consider all relevant factors, including the extent of asset growth of the national bank or Federal savings association since December 31, 2019; the causes of this growth, including whether this growth occurred as a result of a merger or acquisition; whether such growth is likely to be temporary or permanent; whether the national bank or Federal savings association has become involved in any additional activities since December 31, 2019; and the type of assets held by the national bank or Federal savings association. The OCC will notify a national bank or Federal savings association of a determination under this paragraph. A national bank or Federal savings association may, not later than 30 days after the date of a determination by the OCC, inform the OCC, in writing, of why the national bank or Federal savings association should be eligible for the temporary relief. The OCC will make a final determination after reviewing any response.

* * * * *

PART 4—ORGANIZATION AND FUNCTIONS, AVAILABILITY AND RELEASE OF INFORMATION, CONTRACTING OUTREACH PROGRAM, POST-EMPLOYMENT RESTRICTIONS FOR SENIOR EXAMINERS

SUBPART A—Organization and Functions

■ 3. The authority citation for part 4 continues to read as follows: Authority: 5 U.S.C. 301, 552; 12 U.S.C. 1, 93a, 161, 481, 482, 484(a), 1442, 1462a, 1463, 1464 1817(a), 1818, 1820, 1821, 1831m, 1831p–1, 1831o, 1833e, 1867, 1951 *et seq.,* 2601 *et seq.,* 2801 *et seq.,* 2901 *et seq.,* 3101 *et seq.,* 3401 *et seq.,* 5321, 5412, 5414; 15 U.S.C. 77uu(b), 78q(c)(3); 18 U.S.C. 641, 1905, 1906; 29 U.S.C. 1204; 31 U.S.C. 5318(g)(2), 9701; 42 U.S.C. 3601; 44 U.S.C. 3506, 3510; E.O. 12600 (3 CFR, 1987 Comp., p. 235).

■ 4. Section 4.6 is amended by adding paragraph (d) to read as follows:

§ 4.6 Frequency of examination of national banks and Federal savings associations.

* * * * *

(d) Through December 31, 2021, for purposes of determining eligibility for the 18-month rule described in paragraph (b) of this section, the OCC may determine the total assets of a national bank or Federal savings association by reference to the total assets of the national bank or Federal savings association as reported by the national bank or Federal savings association in its Call Report as of December 31, 2019.

■ 5. Section 4.7 is amended by adding paragraph (d) to read as follows:

§ 4.7 Frequency of examination of Federal agencies and branches.

* * * * *

(d) Through December 31, 2021, for purposes of determining eligibility for the 18-month rule described in paragraph (b) of this section, the OCC may determine total assets of a Federal branch or agency by reference to the total assets of the Federal branch or agency as reported by the Federal branch or agency as of December 31, 2019.

PART 52—REGULATORY REPORTING

■ 6. The authority citation for part 52 continues to read as follows:

Authority: 12 U.S.C. 93a, 161, 1463(a), 1464(v), and 1817(a)(12).

■ 7. Add § 52.5 to read as follows:

§ 52.5 Temporary relief.

In determining whether it meets the asset threshold in paragraph (1) of the definition of ''covered depository institution'' in § 52.5 of this part, for purposes of a report required to be submitted for calendar year 2021, a national bank, Federal savings association, or insured Federal branch may refer to the lesser of its total consolidated assets as reported in its report of condition as of December 31, 2019, and its total consolidated assets as reported in its report of condition for the second calendar quarter of 2020.

Board of Governors of the Federal Reserve System

12 CFR Chapter I

Authority and Issuance

For the reasons stated in the joint preamble, chapter II of title 12 of the Code of Federal Regulations is amended as follows:

PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM (REGULATION H)

■ 8. The authority citation for part 208 continues to read as follows:

Authority: 12 U.S.C. 24, 36, 92a, 93a, 248(a), 248(c), 321–338a, 371d, 461, 481–486, 601, 611, 1814, 1816, 1817(a)(3), 1817(a)(12), 1818, 1820(d)(9), 1833(j), 1828(o), 1831, 1831o, 1831p-1, 1831r-1, 1831w, 1831x, 1835a, 1882, 2901–2907, 3105, 3310, 3331–3351, 3905–3909, 5371, and 5371 note; 15 U.S.C. 78b, 78I(b), 78l(i), 780–4(c)(5), 78q, 78q-1, 78w, 1681s, 1681w, 6801, and 6805; 31 U.S.C. 5318; 42 U.S.C. 4012a, 4104a, 4104b, 4106, and 4128.

Subpart C—Bank Securities and Securities-Related Activities

■ 9. Amend § 208.36 by adding paragraph (b)(3) to read as follows:

§ 208.37 Reporting requirements for State member banks subject to the Securities Exchange Act of 1934.

* * * * *

(b) * * *

(3) Notwithstanding paragraph (b)(1) of this section, a member bank may, from December 2, 2020, through December 31, 2021, make the election described in paragraph (b)(1) of this section if it has no foreign offices and had total assets of $150 million or less, determined based on the lesser of total assets as of December 31, 2019, and total assets as of the end of the bank's most recent fiscal year. The relief provided under this paragraph (b)(3) of this section does not apply to a member bank if the Board determines that permitting the member bank to determine its assets in accordance with that paragraph would not be commensurate with the risk profile of the member bank. When making this determination, the Board will consider all relevant factors, including the extent of asset growth of the member bank since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the member bank has become involved in any additional activities since December 31, 2019; the asset size of any parent companies; and the type of assets held by the member bank. In making a determination pursuant to this paragraph (b)(3), the Board will apply notice and response procedures in the same manner and to the same extent as the notice and response procedures in 12 CFR 263.202.

* * * * *

Subpart D—Miscellaneous Requirements

■ 10. Amend § 208.64 by adding paragraph (d) to read as follows:

§ 208.64 Frequency of examination.

* * * * *

(d)(1) Except as provided in paragraph (c) of this section, from December 2, 2020, through December 31, 2021, for purposes of determining eligibility for the extended examination cycle described in paragraph (b) of this section, the total assets of a member bank shall be determined based on the lesser of:

(i) The assets of the member bank as of December 31, 2019; and

(ii) The assets of the member bank as of the end of the most recent calendar quarter.

(2) Nothing in paragraph (d)(1) of this section limits the authority of the Federal Reserve to examine any member bank as frequently as the agency deems necessary pursuant to paragraph (c) of this section.

* * * * *

Subpart K—Forms, Instructions and Reports

■ 11. Amend § 208.121 by revising the definition of ''Covered depository institution'' to read as follows:

§ 208.121 Definitions.

* * * * *

Covered depository institution means a state member bank that meets all of the following criteria:

(1) Has less than $5 billion in total consolidated assets as reported in its report of condition for the second calendar quarter of the preceding year, except that, during the calendar year 2021, a state member bank shall determine whether it meets the requirement in paragraph (1) of this section by using the lesser of its total consolidated assets as reported in its report of condition as of December 31, 2019, and its total consolidated assets as reported in its report of condition for the second calendar quarter of 2020. The relief provided under this paragraph (1) of this section does not apply to a state member bank if the Board determines that permitting the state member bank to determine its assets in accordance with that paragraph would not be commensurate with the risk profile of the state member bank. When making this determination, the Board will consider all relevant factors, including the extent of asset growth of the state member bank since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the state member bank has become involved in any additional activities since December 31, 2019; the asset size of any parent companies; and the type of assets held by the state member bank. In making a determination pursuant to this paragraph (1), the Board will apply notice and response procedures in the same manner and to the same extent as the notice and response procedures in 12 CFR 263.202.

(2) Has no foreign offices, as defined in this section;

(3) Is not required to or has not elected to use 12 CFR part 217, subpart E, to calculate its risk-based capital requirements; and

(4) Is not a large institution or highly complex institution, as such terms are defined in 12 CFR 327.8, or treated as a large institution, as requested under 12 CFR 327.16(f).

* * * * *

PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

■ 12. The authority citation for part 211 continues to read as follows:

Authority: 12 U.S.C. 221 *et seq.,* 1818, 1835a, 1841 *et seq.,* 3101 *et seq.,* 3901 *et seq.,* and 5101 *et seq.;* 15 U.S.C. 1681s, 1681w, 6801 and 6805.

Subpart B—Foreign Banking Organizations

■ 13. Amend § 211.26 by adding paragraph (c)(2)(iii) to read as follows:

§ 211.26 Examination of offices and affiliates of foreign banks.

* * * * *

(c) * * *

(2) * * *

(iii)(A) Except as provided in paragraph (c)(2)(iii)(B) of this section, from December 2, 2020 through December 31, 2021, for purposes of determining eligibility for the extended examination cycle described in paragraph (c)(2) of this section, the total assets of a branch or agency shall be determined based on the lesser of:

(*1*) The total assets of the branch or agency as of December 31, 2019; and

(*2*) The total assets of the branch or agency as of the end of the most recent calendar quarter.

(B) The relief provided under paragraph (c)(2)(iii)(A) of this section does not apply to a branch or agency if the Board determines that permitting the branch or agency to determine its assets in accordance with that paragraph would not be commensurate with the risk profile of the branch or agency. When making this determination, the Board will consider all relevant factors, including the extent of asset growth of the branch or agency since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the branch or agency has become involved in any additional activities since December 31, 2019; the asset size of any parent companies; and the type of assets held by the branch or agency. In making a determination pursuant to this paragraph (c)(2)(iii)(B), the Board will apply notice and response procedures in the same manner and to the same extent as the notice and response procedures in 12 CFR 263.202.

* * * * *

PART 212—MANAGEMENT OFFICIAL INTERLOCKS

■ 14. The authority citation for part 212 continues to read as follows:

Authority: 12 U.S.C. 3201–3208; 15 U.S.C. 19.

■ 15. Amend § 212.2 by adding paragraph (o)(3) to read as follows:

§ 212.2 Definitions.

* * * * *

(o) * * *

(3)(i) Notwithstanding paragraph (o)(1) of this section, and except as provided in paragraph (o)(3)(ii) of this section, from December 2, 2020, through December 31, 2021, the term *total assets,* with respect to a depository organization, means the lesser of assets of the depository organization reported on a consolidated basis as of December 31, 2019, and assets reported as of the end of the depository organization's most recent fiscal year on a consolidated basis as of December 31, 2020.

(ii) The relief provided under paragraph (o)(3)(i) of this section does not apply to a depository organization if the Board determines that permitting the depository organization to determine its assets in accordance with that paragraph would not be commensurate with the risk profile of the depository organization. When making this determination, the Board will consider all relevant factors, including the extent of asset growth of the depository organization since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the depository organization has become involved in any additional activities since December 31, 2019; the asset size of any parent companies; and the type of assets held by the depository organization. In making a determination pursuant to this paragraph (o)(3)(ii), the Board will apply notice and response procedures in the same manner and to the same extent as the notice and response procedures in 12 CFR 263.202.

* * * * *

PART 217—CAPITAL ADEQUACY OF BANK HOLDING COMPANIES, SAVINGS AND LOAN HOLDING COMPANIES, AND STATE MEMBER BANKS (REGULATION Q)

■ 16. The authority citation for part 217 continues to read as follows:

Authority: 12 U.S.C. 248(a), 321–338a, 481–486, 1462a, 1467a, 1818, 1828, 1831n, 1831o, 1831p–1, 1831w, 1835, 1844(b), 1851, 3904, 3906–3909, 4808, 5365, 5368, 5371, 5371 note, and sec. 4012, Pub. L. 116–136, 134 Stat. 281.

Subpart B—Capital Ratio Requirements and Buffers

■ 17. Amend § 217.12 by adding paragraph (a)(4) to read as follows:

§ 217.12 Community bank leverage ratio framework.

(a) * * *

(4) *Temporary relief for 2020 and 2021.* (i) Except as provided in paragraph (a)(4)(ii) of this section, from December 2, 2020, through December 31, 2021, for purposes of determining whether a Board-regulated institution satisfies the criterion in paragraph (a)(2)(ii) of this section, the total consolidated assets of a Board-regulated institution for purposes of paragraph (a)(2)(ii) of this section shall be determined based on the lesser of:

(A) The total consolidated assets reported by the institution in the Call Report, FR Y–9C, or FR Y–9SP, as applicable, as of December 31, 2019; and

(B) The total consolidated assets calculated in accordance with the reporting instructions to the Call Report or to Form FR Y–9C, as applicable, as of the end of the most recent calendar quarter.

(ii) The relief provided under this paragraph (a)(4)(i) does not apply to a Board-regulated institution if the Board determines that permitting the Board-regulated institution to determine its assets in accordance with that paragraph would not be commensurate with the risk profile of the Board-regulated institution. When making this determination, the Board will consider all relevant factors, including the extent of asset growth of the Board-regulated institution since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the Board-regulated institution has become involved in any additional activities since December 31, 2019; the asset size of any parent companies; and the type of assets held by the Board-regulated institution. In making a determination pursuant to this paragraph (a)(4)(ii), the Board will apply notice and response procedures in the same manner and to the same extent as the notice and response procedures in 12 CFR 263.202.

* * * * *

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

■ 18. The authority citation for part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1844(b), 1972(1), 3106, 3108, 3310, 3331–3351, 3906, 3907, and 3909; 15 U.S.C. 1681s, 1681w, 6801 and 6805.

Subpart A—General Provisions

■ 19. Add § 225.10 to subpart A to read as follows:

§ 225.10 Temporary relief for 2020 and 2021.

(a) Except as provided in paragraph (c) of this section and subject to the provisions of paragraph (d) of this section, from December 2, 2020, through December 31, 2021, the consolidated assets, consolidated risk-weighted assets, total consolidated assets, and total assets of a bank holding company for purposes of §§ 225.4(b)(2)(iii)(A) and (B), 225.14(a)(1)(v)(A)(*1*) and (*2*), 225.14(a)(1)(vi), 225.23(a)(1)(iii)(A)(*1*) and (*2*), 225.24(a)(2)(iv) and (v), and 225.28(b)(11)(vi) shall be determined based on the lesser of each such amount as of December 31, 2019, and as of the otherwise applicable asset measurement date of the relevant paragraph.

(b) Except as provided in paragraph (c) of this section and subject to the provisions of paragraph (d) of this section, from December 2, 2020, through December 31, 2021, for purposes of determining the applicability of §§ 224.14(c)(6)(ii), 225.17(a)(6), and 225.23(c)(5)(ii) of this part and appendix C to this part, the *pro forma* consolidated assets of a bank holding company and the consolidated risk-weighted assets of a bank holding company immediately following consummation of a transaction each shall be calculated as the lesser of:

(1) Such amount calculated as the sum of the assets of each company involved in the proposed business combination, as well as any company with which any such company has combined since December 31, 2019, as of December 31, 2019; and

(2) Such amount calculated as the sum of the assets of each company involved in the proposed business combination as of the end of the most recent calendar quarter.

(c) The relief provided under paragraphs (a) and (b) of this section does not apply to a bank holding company if the Board determines that permitting the bank holding company to determine its assets in accordance with that paragraph would not be commensurate with the risk profile of the bank holding company. When making this determination, the Board will consider all relevant factors, including the extent of asset growth of the bank holding company since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the bank holding company has become involved in any additional activities since December 31, 2019; the asset size of any parent companies; and the type of assets held by the bank holding company. In making a determination pursuant to this section, the Board will apply notice and response procedures in the same manner and to the same extent as the notice and response procedures in 12 CFR 263.202.

(d) Nothing in this section limits the discretion of the Board or its delegatee to disallow the use of any expedited action process, require the submission of additional information in connection with a notice or application, or consider the ability of a bank holding company filing a notice or application under this part to comply with any statutory or regulatory requirements that may be applicable to the bank holding company upon expiration of the relief provided by this section.

PART 235—DEBIT CARD INTERCHANGE FEES AND ROUTING (REGULATION II)

■ 20. The authority citation for part 235 continues to read as follows:

Authority: 15 U.S.C. 1693o–2.

■ 21. The heading for part 235 is revised to read as set forth above.

■ 22. Amend § 235.5 by adding paragraph (a)(4) to read as follows:

§ 235.5 Exemptions.

* * * * *

(a) * * *

(4)(i) *Temporary relief for 2020 and 2021.* Except as provided in paragraph (a)(4)(ii) of this section, for purposes of determining eligibility for the exemption for small issuers described in paragraph (a)(1) of this section, issuer asset size that is calculated as of the end of the calendar year 2020 shall be determined based on the lesser of:

(A) The assets of the issuer, together with its affiliates, as of the end of the calendar year 2019; and

(B) The assets of the issuer, together with its affiliates, as of the end of the calendar year 2020.

(ii) The relief provided under this paragraph (a)(4) does not apply to an issuer if the Board determines that permitting the issuer to determine its assets in accordance with that paragraph would not be commensurate with the asset profile of the issuer. When making this determination, the Board will consider all relevant factors, including the extent of asset growth of the issuer since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the issuer has become involved in any additional activities since December 31, 2019; the asset size of any parent companies; and the type of assets held by the issuer. In making a determination pursuant to this paragraph (a)(4)(ii), the Board will apply notice and response procedures in the same manner and to the same extent as the notice and response procedures in 12 CFR 263.202.

* * * * *

PART 238—SAVINGS AND LOAN HOLDING COMPANIES (REGULATION LL)

■ 23. The authority citation for part 238 continues to read as follows:

Authority: 5 U.S.C. 552, 559; 12 U.S.C. 1462, 1462a, 1463, 1464, 1467, 1467a, 1468, 5365; 1813, 1817, 1829e, 1831i, 1972, 15 U.S.C. 78*l*.

Subpart A—General Provisions

■ 24. Amend § 238.5 by revising paragraph (b) to read as follows:

§ 238.5 Audit of savings association holding companies.

* * * * *

(b) *Audits required for safety and soundness purposes.* (1) The Board requires an independent audit for safety and soundness purposes if, as of the beginning of its fiscal year, a savings and loan holding company controls savings association subsidiary(ies) with aggregate consolidated assets of $500 million or more.

(2) Except as provided in paragraph (b)(3) of this section, with regard to a savings and loan holding company's fiscal year beginning in the calendar years 2020 or 2021, the applicability of the requirement in paragraph (b)(1) of this section shall be determined based on the lesser of:

(i) The aggregate consolidated assets of the savings and loan holding company as of December 31, 2019; and

(ii) The aggregate consolidated assets of the savings and loan holding company as of the end of its fiscal year ending in calendar year 2020.

(3) The relief provided under paragraph (b)(2) of this section does not apply to a savings and loan holding company if the Board determines that permitting the savings and loan holding company to determine its assets in accordance with that paragraph would not be commensurate with the risk profile of the savings and loan holding company. When making this determination, the Board will consider all relevant factors, including the extent of asset growth of the savings and loan holding company since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the savings and loan holding company has become involved in any additional activities since December 31, 2019; the asset size of any parent companies; and the type of assets held by the savings and loan holding company. In making a determination pursuant to this paragraph (b)(3), the Board will apply notice and response procedures in the same manner and to the same extent as the notice and response procedures in 12 CFR 263.202.

* * * * *

Subpart F—Savings and Loan Holding Company Activities and Acquisitions

■ 25. Amend § 238.53 by adding paragraph (c)(3) to read as follows:

§ 238.53 Prescribed services and activities of savings and loan holding companies.

* * * * *

(c) * * *

(3)(i) Except as provided in paragraph (c)(3)(ii) of this section, from December 2, 2020, until December 31, 2021, the determination of whether a savings and loan holding company must comply with the filing requirements in paragraph (c)(2)(iii) or (iv) of this section shall be made based on the lesser of:

(A) The consolidated assets of the savings and loan holding company as of December 31, 2019; and

(B) The consolidated assets of the savings and loan holding company as of the end of the most recent calendar quarter.

(ii) The relief provided under paragraph (c)(3)(i) of this section does not apply to a savings and loan holding company if the Board determines that permitting the savings and loan holding company to determine its assets in accordance with that paragraph would not be commensurate with the risk profile of the savings and loan holding company. When making this determination, the Board will consider all relevant factors, including the extent of asset growth of the savings and loan holding company since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the savings and loan holding company has become involved in any additional activities since December 31, 2019; the asset size of any parent companies; and the type of assets held by the savings and loan holding company. In making a determination pursuant to this paragraph (c)(3)(ii), the Board will apply notice and response procedures in the same manner and to the same extent as the notice and response procedures in 12 CFR 263.202.

* * * * *

Subpart J—Management Official Interlocks

■ 26. Amend § 238.92 by adding paragraph (p)(3) to read as follows:

§ 238.92 Definitions.

* * * * *

(p) * * *

(3) *Temporary relief for 2020 and 2021.* Notwithstanding paragraph (p)(1) of this section, from December 2, 2020, through December 31, 2021, for purposes of this subpart J, the term *total assets,* with respect to a depository organization, means the lesser of assets of the depository organization reported on a consolidated basis as of December 31, 2019, and assets reported on a consolidated basis as of the end of the most recent fiscal year. The relief provided under this paragraph (p)(3) does not apply to a depository organization if the Board determines that permitting the depository organization to determine its assets in accordance with that paragraph would not be commensurate with the risk profile of the depository organization. When making this determination, the Board will consider all relevant factors, including the extent of asset growth of the depository organization since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the depository organization has become involved in any additional activities since December 31, 2019; the asset size of any parent companies; and the type of assets held by the depository organization. In making a determination pursuant to this paragraph (p)(3), the Board will apply notice and response procedures in the same manner and to the same extent as the notice and response procedures in 12 CFR 263.202.

* * * * *

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Chapter III

Authority and Issuance

For the reasons stated in the preamble, the Federal Deposit Insurance Corporation amends chapter III of Title 12, Code of Federal Regulations as follows:

PART 304—FORMS, INSTRUCTIONS, AND REPORTS

■ 27. The authority citation for part 304 continues to read as follows:

Authority: 12 U.S.C. 1464(v), 1817(a), and 1819 Tenth.

■ 28. Amend § 304.12 by adding paragraph (a)(6) to read as follows:

§ 304.12 Definitions.

(a) * * *

(6) In determining whether an insured depository institution meets the asset threshold in paragraph (1) of the definition of ''covered depository institution'' in paragraph (a)(1) of this section, for purposes of a report required to be submitted for calendar year 2021, an insured depository institution may refer to the lesser of its total consolidated assets as reported in its report of condition as of December 31, 2019, and its total consolidated assets as reported in its report of condition for the second calendar quarter of 2020.

PART 324—CAPITAL ADEQUACY OF FDIC-SUPERVISED INSTITUTIONS

■ 29. The authority citation for part 324 is revised to read as follows:

Authority: 12 U.S.C. 1815(a), 1815(b), 1816, 1818(a), 1818(b), 1818(c), 1818(t), 1819(Tenth), 1828(c), 1828(d), 1828(i), 1828(n), 1828(o), 1831o, 1835, 3907, 3909, 4808; 5371; 5412; Pub. L. 102–233, 105 Stat. 1761, 1789, 1790 (12 U.S.C. 1831n note); Pub. L. 102–242, 105 Stat. 2236, 2355, as amended by Pub. L. 103–325, 108 Stat. 2160, 2233 (12 U.S.C. 1828 note); Pub. L. 102–242, 105 Stat. 2236, 2386, as amended by Pub. L. 102–550, 106 Stat. 3672, 4089 (12 U.S.C. 1828 note); Pub. L. 111–203, 124 Stat. 1376, 1887 (15 U.S.C. 78o–7 note), Pub. L. 115–174; section 4014 § 201, Pub. L. 116–136, 134 Stat. 281 (15 U.S.C. 9052).

■ 30. Amend § 324.12 by adding paragraph (a)(4) to read as follows:

§ 324.12 Community bank leverage ratio framework.

(a) * * *

(4)(i) *Temporary relief*—From December 2, 2020 through December 31, 2021, for purposes of determining whether an FDIC-supervised institution satisfies the criterion in paragraph (a)(2)(ii) of this section, except as provided in paragraph (a)(4)(ii) of this section, the total consolidated assets of an FDIC-supervised institution for purposes of paragraph (a)(2)(ii) of this section shall be determined based on the lesser of:

(A) The total consolidated assets reported by the institution in the Call Report as of December 31, 2019; and

(B) The total consolidated assets calculated in accordance with the reporting instructions to the Call Report as of the end of the most recent calendar quarter.

(ii) *Reservation of authority*—The temporary relief provided under this paragraph (a)(4)(i) of this section does not apply to an FDIC-supervised institution if the FDIC determines that permitting the FDIC-supervised institution to determine its assets in accordance with that paragraph would not be commensurate with the risk posed by the institution. When making this determination, the FDIC will consider all relevant factors, including the extent of asset growth of the FDIC-supervised institution since December

31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the FDIC-supervised institution has become involved in any additional activities since December 31, 2019; and the type of assets held by the FDIC-supervised institution. The FDIC will notify an FDIC-supervised institution of a determination under this paragraph. An FDIC-supervised institution may, not later than 30 days after the date of a determination by the FDIC, inform the FDIC, in writing, of why the FDIC-supervised institution should be eligible for the temporary relief. The FDIC will make a final determination after reviewing any response.

* * * * *

PART 337—UNSAFE AND UNSOUND BANK PRACTICES

■ 31. The authority citation for part 337 continues to read as follows:

Authority: 12 U.S.C. 375a(4), 375b, 1463, 1464, 1468, 1816, 1818(a), 1818(b), 1819, 1820(d), 1821(f), 1828(j)(2), 1831, 1831f, 1831g, 5412.

■ 32. Amend § 337.12 by adding paragraph (d) to read as follows:

§ 337.12 Frequency of examination.

* * * * *

(d) From December 2, 2020, through December 31, 2021, for purposes of determining eligibility for the extended examination cycle described in paragraph (b) of this section, the total assets of an institution shall be determined based on the lesser of:

(1) The assets of the institution as of December 31, 2019; and

(2) The assets of the institution as of the end of the most recent calendar quarter.

PART 347—INTERNATIONAL BANKING

■ 33. The authority citation for part 347 continues to read as follows:

Authority: 12 U.S.C. 1813, 1815, 1817, 1819, 1820, 1828, 3103, 3104, 3105, 3108, 3109; Pub. L. 111–203, section 939A, 124 Stat. 1376, 1887 (July 21, 2010) (codified 15 U.S.C. 78o–7 note).

■ 34. Amend § 347.211 by adding paragraph (d) to read as follows:

§ 347.21 Examination of branches of foreign banks.

* * * * *

(d) From December 2, 2020, through December 31, 2021, for purposes of determining eligibility for the extended examination cycle described in paragraph (b) of this section, the total assets of an insured branch shall be determined based on the lesser of:

(1) The assets of the insured branch as of December 31, 2019; and

(2) The assets of the insured branch as of the end of the most recent calendar quarter.

PART 348—MANAGEMENT OFFICIAL INTERLOCKS

■ 35. The authority citation for part 348 continues to read as follows:

Authority: 12 U.S.C. 1823(k), 3207.

■ 36. Amend § 348.2 by adding paragraph (q)(3) to read as follows:

§ 348.2 Other definitions and rules of construction.

* * * * *

(q) * * *

(3)(i) *Temporary relief for 2020 and 2021.* Notwithstanding paragraph (q)(1) of this section, from December 2, 2020, through December 31, 2021, except as provided in paragraph (q)(3)(ii) of this section, the term *total assets,* with respect to a depository organization, means the lesser of assets of the depository organization reported on a consolidated basis as of December 31, 2019, and assets reported on a consolidated basis as of December 31, 2020.

(ii) *Reservation of authority.* The temporary relief provided under this paragraph (q)(3)(i) of this section does not apply to an FDIC-supervised institution if the FDIC determines that permitting the FDIC-supervised institution to determine its assets in accordance with that paragraph would not be commensurate with the risk posed by the institution. When making this determination, the FDIC will consider all relevant factors, including the extent of asset growth of the FDIC-supervised institution since December 31, 2019; the causes of such growth, including whether growth occurred as a result of mergers or acquisitions; whether such growth is likely to be temporary or permanent; whether the FDIC-supervised institution has become involved in any additional activities since December 31, 2019; and the type of assets held by the FDIC-supervised institution.

* * * * *

Brian P. Brooks,

Acting Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on or about November 17, 2020.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2020–26138 Filed 12–1–20; 8:45 am]

BILLING CODE 6210–01–P

FARM CREDIT ADMINISTRATION

12 CFR Part 614

RIN 3052–AC92

Amortization Limits; Correction

AGENCY: Farm Credit Administration.

ACTION: Final rule; correction.

SUMMARY: On September 28, 2020, the Farm Credit Administration (FCA) published a final rule that repealed the regulatory requirement that production credit associations (PCAs) amortize their loans in 15 years or less, while requiring all Farm Credit System (FCS or System) associations to address amortization through their credit underwriting standards and internal controls. In that publication, FCA inadvertently omitted a statement that the Office of Management and Budget's Office of Information and Regulatory Affairs determined that the final rule is not a major rule under the applicable provisions of the Congressional Review Act. This document corrects that error.

DATES: This correction is effective December 2, 2020.

FOR FURTHER INFORMATION CONTACT: Richard A. Katz, Senior Counsel, Office of General Counsel, (703) 883–4020, TTY (703) 883–4056, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

SUPPLEMENTARY INFORMATION: In FR Doc. 2020–18552, entitled ''Amortization Limits,'' beginning on page 60691 in the **Federal Register** of Monday, September 28, 2020, make the following corrections;

1. On page 60693, in the second column, the heading for section V is corrected to read ''Regulatory Flexibility Act and Major Rule Conclusion.''

2. On page 60693, in the second column, add paragraph at the end of section V to read as follows:

Under the provisions of the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Management and Budget's Office of Information and Regulatory Affairs has determined that this final rule is not a ''major rule,'' as the term is defined at 5 U.S.C. 804(2).

Dated: October 21, 2020.

Dale Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2020–23688 Filed 12–1–20; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9935]

RIN 1545–BP02

Statutory Limitations on Like-Kind Exchanges

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations providing guidance under section 1031 of the Internal Revenue Code (Code) to implement recent statutory changes to that section. More specifically, the final regulations amend the current like-kind exchange regulations to add a definition of real property to implement statutory changes limiting section 1031 treatment to like-kind exchanges of real property. The final regulations also provide a rule addressing a taxpayer's receipt of personal property that is incidental to real property the taxpayer receives in an otherwise qualifying like-kind exchange of real property. The final regulations affect taxpayers that exchange business or investment property for other business or investment property, and that must determine whether the exchanged properties are real property under section 1031.

DATES:

Effective date: These final regulations are effective on December 2, 2020.

Applicability dates: These regulations generally apply to exchanges beginning after December 2, 2020. See §§ 1.1031(a)–1(e)(2), 1.1031(a)–3(c), and 1.1031(k)–1(g)(9). However, the regulations in §§ 1.168(i)–1(e)(2)(viii)(A) and 1.168(i)–8(c)(4)(i) apply to taxable years beginning after December 2, 2020. See §§ 1.168(i)–1(m)(5) and 1.168(i)–8(j)(5).

FOR FURTHER INFORMATION CONTACT: Edward C. Schwartz at (202) 317–4740, or Suzanne R. Sinno at (202) 317–4718 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

I. Overview

This document amends the Income Tax Regulations (26 CFR part 1, as revised April 1, 2020) under section 1031 (current regulations). The amendments to the current regulations (final regulations) implement statutory amendments to section 1031 made by section 13303 of Public Law 115–97, 131 Stat. 2054 (2017), commonly referred to as the Tax Cuts and Jobs Act (TCJA). Section 13303(c) of the TCJA amended section 1031 to limit its application to exchanges of real property for exchanges completed after December 31, 2017, subject to a transition rule for certain exchanges in which property had been transferred before January 1, 2018. To implement these statutory changes, the final regulations limit the application of the like-kind exchange rules under section 1031 to exchanges of real property, add a definition of real property, and adapt an existing incidental property exception to apply to a taxpayer's receipt of personal property that is incidental to real property the taxpayer receives in the exchange.

II. Section 1031 After the TCJA

As amended by the TCJA, section 1031(a) provides that no gain or loss is recognized on the exchange of real property held for productive use in a trade or business or for investment (relinquished real property) if the relinquished real property is exchanged solely for real property of a like kind that is to be held either for productive use in a trade or business or for investment (replacement real property). The legislative history to the TCJA amendments to section 1031 provides that Congress ''intended that real property eligible for like-kind exchange treatment under present law will continue to be eligible for like-kind exchange treatment under the [amended] provision.'' H.R. Conf. Rept. 115–466, at 396, fn. 726 (2017) (Conference Report). However, left unchanged by the TCJA, section 1031(b) provides that a taxpayer must recognize gain to the extent of money and non-like-kind property the taxpayer receives in an exchange.

III. Current Regulations Regarding ''Like Kind''

The need to determine whether the relinquished real property and the replacement real property are of a like kind continues to exist after the changes to section 1031 made by the TCJA. Current § 1.1031(a)–1(b) provides that ''like kind'' refers to the nature or character of the real property and not to its grade or quality. The fact that any real property involved is improved or unimproved is not material in determining whether real property is of like kind. Under current § 1.1031(a)–1(c), examples of exchanges of real property of a like kind include an exchange of a leasehold interest in a fee with 30 years or more to run for real estate.

IV. Identification of Exchanged Properties

Under section 1031(a)(3), unchanged by the TCJA, real property a taxpayer receives in an exchange is not of like-kind to the relinquished property unless, within 45 days after the taxpayer's transfer of the relinquished real property, the real property is identified as replacement real property to be received in the exchange. Current § 1.1031(k)–1(c)(4) provides a limit on the number of properties, or the fair market value of the properties, a taxpayer may identify to meet the requirements of section 1031(a)(3). However, under current § 1.1031(k)–1(c)(5), property is disregarded in evaluating the identification rules if it is incidental to a larger item of property and therefore, is not treated as property separate from the larger item. Property is incidental to a larger property if, in standard commercial transactions, the property is typically transferred with the larger item of property, and the aggregate fair market value of all of the incidental property does not exceed 15 percent of the aggregate fair market value of the larger item of property.

V. Recognition of Gain or Loss on Actual or Constructive Receipt of Non-Like-Kind Property

Under current § 1.1031(k)–1(f)(1) and (2), if a taxpayer actually or constructively receives money or non-like-kind property for the relinquished property before the taxpayer receives like-kind replacement real property, the transaction is a sale or taxable exchange and not a like-kind exchange, even though the taxpayer may ultimately receive like-kind replacement real property. Current § 1.1031(k)–1(g)(2) through (5) provides safe harbors, the use of which results in a taxpayer not being considered in actual or constructive receipt of the consideration for the relinquished property.

Under current § 1.1031(k)–1(g)(4)(i), in the case of a taxpayer's transfer of relinquished property involving a qualified intermediary, the determination of whether the taxpayer is in actual or constructive receipt of money or non-like-kind property is made as if the qualified intermediary is not the agent of the taxpayer. However, current § 1.1031(k)–1(g)(4)(i) applies only if the agreement between the taxpayer and the qualified intermediary

expressly limits the taxpayer's rights to receive, pledge, borrow, or otherwise obtain the benefits of money or non-like-kind property held by the qualified intermediary. Current § 1.1031(k)–1(g)(7) lists items received in an exchange that are disregarded in determining whether a taxpayer's rights to receive, pledge, borrow, or otherwise obtain the benefits of money or non-like-kind property are expressly limited.

VI. Proposed Regulations

On June 12, 2020, the Department of the Treasury (Treasury Department) and the IRS published a notice of proposed rulemaking (REG–117589–18) in the **Federal Register** (85 FR 35835) containing proposed regulations under section 1031 (proposed regulations). The Treasury Department and the IRS received 21 written comments in response to the notice of proposed rulemaking. All comments were considered and are available at *http://www.regulations.gov* or upon request. A public hearing on the proposed regulations was neither requested nor held. After full consideration of the comments received, this Treasury decision adopts the proposed regulations with modifications in response to such comments, as described in the Summary of Comments and Explanation of Revisions following this Background.

Summary of Comments and Explanation of Revisions

I. Overview

The final regulations retain the basic approach and structure of the proposed regulations, with certain revisions. In particular, the final regulations revise the definition of ''real property'' in the proposed regulations to provide that property is classified as real property for section 1031 purposes if, on the date it is transferred in an exchange, the property is real property under the law of the State or local jurisdiction in which that property is located. The final regulations also revise the proposed definition of real property to eliminate, with regard to both tangible and intangible properties, any consideration of whether the particular property contributes to the production of income unrelated to the use or occupancy of space (referred to as the ''purpose or use test,'' as defined in part II.B.1 of this Summary of Comments and Explanation of Revisions). Finally, in § 1.1031(a)–3(a)(7), the final regulations retain the language of the proposed regulations clarifying that the rules of these final regulations apply only for purposes of section 1031, and that no inference is intended with respect to the classification or characterization of property for other purposes of the Code.

II. Definition of Real Property

A. State or Local Law Definitions of Real Property

1. Approach of the Proposed Regulations

Section 1031 does not provide a definition for the term ''real property.'' As noted in part II of the Background section, the Conference Report provides that Congress intended real property that was eligible for like-kind exchange treatment prior to the enactment of the TCJA to continue to be eligible for like-kind exchange treatment after its enactment. See Conference Report, at 396, fn. 726. Specifically, with regard to the applicability of State law for real property determinations, the Conference Report sets forth the following example: ''a like-kind exchange of real property includes an exchange of shares in a mutual ditch, reservoir, or irrigation company described in section 501(c)(12)(A) [of the Code] if at the time of the exchange such shares have been recognized by the highest court or statute of the State in which the company is organized as constituting or representing real property or an interest in real property'' (Conference Report Example). Id. Accordingly, due to the absence of a statutory definition for the term ''real property'' in section 1031, the Treasury Department and the IRS based the proposed definition of real property upon the Conference Report Example.

Under proposed § 1.1031(a)–3(a)(1), State law controls whether shares in a mutual ditch, reservoir, or irrigation company are real property for purposes of section 1031. Aside from those enumerated asset types, the proposed regulations provide that State or local law definitions were not controlling for purposes of determining whether property is real property for section 1031 purposes. See proposed § 1.1031(a)–3(a)(1). The intent of the Treasury Department and the IRS in proposing a rule that expressly applied State or local law in this manner was to provide a definition of real property for purposes of section 1031 ''in a manner consistent with the scope described by Congress in the Conference Report.'' See the preamble to the proposed regulations at 85 FR 35836.

2. Consideration of Comments and Revision of ''Real Property'' Definition

Commenters generally critiqued the apparent scope of the application of State and local law in the proposed regulations for purposes of defining real property. These commenters contended that, prior to enactment of the TCJA, State and local law classification of a property often was the determining factor in characterizing property as real or personal under section 1031. With regard to the Conference Report Example, the commenters asserted that the reference to ''shares in a mutual ditch, reservoir, or irrigation company'' merely constituted a set of examples that Congress provided to broadly indicate that real property eligible for like-kind treatment under law prior to enactment of the TCJA will continue to be eligible following the TCJA's amendment to section 1031. Consequently, the commenters recommended that the final regulations conform to that intent by expanding the rules to rely significantly, or wholly, on State-law classifications for all assets, rather than limiting such reliance to shares in a mutual ditch, reservoir, or irrigation company. Additionally, commenters suggested that the final regulations should include multiple examples of instances in which taxpayers may rely on State or local law for purposes of classifying property as real or personal.

In light of these comments, the Treasury Department and the IRS have reconsidered the degree to which State or local law determinations of real property should be controlling for defining real property for section 1031 purposes. As a result of that reconsideration, the final regulations provide generally that property is real property for purposes of section 1031 if, on the date it is transferred in an exchange, that property is classified as real property under the law of the State or local jurisdiction in which that property is located (State and local law test). The State and local law test applies to both tangible and intangible property classifications.

However, consistent with Congressional intent that ''real property eligible for like-kind exchange treatment'' under the law in effect prior to enactment of the TCJA will continue to be eligible for like-kind exchange treatment after enactment of the TCJA, property ineligible for like-kind exchange treatment prior to enactment of the TCJA remains ineligible, including real property that was excluded from the application of section 1031. See Conference Report at 396, fn. 726. Prior to amendment by the TCJA, former section 1031(a)(2) explicitly excluded certain assets from the application of section 1031. Accordingly, the final regulations exclude from the definition of real

property the intangible assets listed in section 1031(a)(2) prior to its amendment by the TCJA, regardless of the classification of the property under State or local law, because such property never was ''real property *eligible* for like-kind exchange treatment'' prior to enactment of the TCJA. Conference Report at 396, fn. 726 (emphasis added).

In summary, under the final regulations, property is classified as real property for purposes of section 1031 if the property is (i) so classified under the State and local law test, subject to certain exceptions, (ii) specifically listed as real property in the final regulations, or (iii) considered real property based on all the facts and circumstances under the various factors provided in the final regulations. A determination that property is personal property under State or local law does not preclude the conclusion that property is real property as specifically listed in § 1.1031(a)–3(a)(2)(ii) or (a)(2)(iii)(B) or under the factors listed in § 1.1031(a)–3(a)(2)(ii)(C) or (a)(2)(iii)(B).

3. Chief Counsel Advice (CCA) 201238027

Multiple commenters who objected to the scope of State and local law determinations under the proposed regulations also asserted that the approach in the proposed regulations replicated the analysis in CCA 201238027 (April 17, 2012), particularly with regard to one of the fact patterns addressed therein regarding a steam turbine (Case 3). In Case 3, the Chief Counsel Advice disregarded State law that characterized the steam turbine as real property and held that the steam turbine was not of like kind to land because it did not have the same nature or character as land. Commenters objected to this conclusion, contending that the State law classification of the steam turbine as real property should be respected and, based on that classification, the steam turbine and the undeveloped land should be considered like-kind property.

These final regulations do not address whether exchanged properties are of like kind to one another. As a consequence of expressly including the State and local law test in the final regulations, the final regulations do not adopt the reasoning of CCA 201238027 to the extent it suggests that State or local law is disregarded in determining whether property is real property under section 1031.

4. Additional Comments Regarding the Application of State and Local Law

In connection with the State and local law test under the final regulations, the Treasury Department and the IRS have considered numerous additional comments. For instance, one commenter recommended that any asset determined to be essentially the same as an asset classified as a real property for purposes of section 1031 also should automatically be treated as real property for purposes of section 1031. For example, if one asset (Property A) is classified as real property under the State or local law of State X, an asset located in a different jurisdiction (Property B) that is essentially the same as Property A also should be classified as real property for section 1031 purposes, irrespective of whether Property B is classified as real property under (i) the law of the State or local jurisdiction in which Property B is located or (ii) the real property definition and factors under the proposed regulations.

The final regulations do not adopt this suggestion. First, the Treasury Department and the IRS have determined that the ''essentially the same'' standard recommended by the commenter would be difficult for taxpayers to apply and the IRS to administer with certainty. In addition, the analysis advocated by the commenter is conceptually similar to the analysis applied by CCA 201238027, which, based on several other comments, the Treasury Department and the IRS have determined to be inconsistent with the State and local law test provided in the final regulations.

A commenter also requested that the final regulations classify as real property all property that was treated as real property for section 1031 purposes at any time between May 22, 2008, and the effective date of the TCJA. May 22, 2008, is the effective date of former section 1031(i), which treats shares in certain mutual ditch companies as real property for section 1031 purposes. The commenter reasoned that, because the treatment of mutual ditch company shares has been preserved by the proposed regulations following the enactment of the TCJA, all property classified as real property as of May 22, 2008, also should be classified as real property under the final regulations.

The final regulations do not adopt the commenter's suggestion. The Treasury Department and the IRS have determined that a rule that fixes property classifications under State or local laws as of a date certain would add complexity as the post-enactment period of the TCJA continues to lengthen. Given that the final regulations have broadened the applicability of State and local real property classification for purposes of section 1031 qualification, the Treasury Department and the IRS have determined that the perpetually increasing complexity of such a rule would significantly outweigh any potential benefits of the commenter's suggestion.

B. Purpose or Use Test

1. Approach of the Proposed Regulations

Under proposed § 1.1031(a)–3(a)(1), real property includes land and improvements to land, and improvements to land include both inherently permanent structures and the structural components of inherently permanent structures. Inherently permanent structures are buildings or other structures that are permanently affixed to real property and that will ordinarily remain affixed for an indefinite period of time. See proposed § 1.1031(a)–3(a)(2)(ii)(A). A list of structures that qualify as buildings or as other inherently permanent structures is provided in proposed § 1.1031(a)–3(a)(2)(ii)(B) and (C). A structural component is any distinct asset, as defined in the proposed regulations, that is a constituent part of, and integrated into, an inherently permanent structure. See proposed § 1.1031(a)–3(a)(2)(iii)(A). Proposed § 1.1031(a)–3(a)(2)(iii)(B) provides examples of items that are structural components under section 1031.

The proposed regulations also consider the function of property in determining whether the property is real property for section 1031 purposes (purpose or use test). In particular, neither tangible property, such as machinery or equipment, nor intangible property, such as licenses or permits, is classified as real property under the proposed regulations if the property contributes to the production of income unrelated to the use or occupancy of space, irrespective of any other factor under the proposed regulations. See proposed §§ 1.1031(a)–3(a)(2)(ii)(D) (regarding machinery and equipment) and 1.1031(a)–3(a)(5) (regarding intangible property). For example, a gas line installed for the sole purpose of providing fuel to fryers and ovens in a restaurant is not a constituent part of an inherently permanent structure and therefore not real property under the proposed regulations. See also proposed § 1.1031(a)–3(b)(12) (providing a similar

example with regard to a license to operate a casino business, which is an intangible property). The proposed regulations requested comments on whether the purpose or use test is appropriate to use as the basis for determining whether property qualifies as real property for section 1031 purposes.

2. Summary of Comments Received

Commenters uniformly disagreed with the purpose or use test and advocated that it be omitted from the final regulations. According to these commenters, the purpose or use test improperly narrows the scope of the definition of real property for section 1031 purposes and, if adopted in the final regulations, would treat certain types of property that have historically been treated as real property for section 1031 purposes as personal property contrary to the directive of Congress in the Conference Report. See Conference Report, at 396, fn. 726.

In addition, commenters contend that machinery and equipment should not be disqualified as an inherently permanent structure, and thus as real property, merely because the machinery or equipment is used in the production of income unrelated to use or occupancy of space. Instead, the commenters asserted that if such property is inherently permanent, the property should be treated as real property for purposes of section 1031, regardless of its purpose or use or the type of income it generates. Therefore, according to the commenters, permanently affixed items such as gas lines, cooling units, and piping should be treated as real property without regard to whether those items comprise part of an income-generating structure. The commenters also recommended that the final regulations provide revised examples to reflect the position that the real property characterization of a particular asset is based on the degree to which the item is permanently affixed and not on its purpose and use.

One commenter also emphasized that the purpose or use test would prove burdensome for small businesses and individual taxpayers because that test would require them to expend resources on cost segregation studies to determine which items of machinery and equipment are personal and which are real property. According to the commenter, such expenses would be eliminated if real property determinations are based on permanent affixation and not purpose or use. Finally, the commenter noted that inclusion of the purpose or use test in the final regulations would be problematic because neither section 1031 nor the regulations under section 1031 provide a definition of machinery. However, the term ''machinery'' is not necessary if, as this commenter recommended, real property determinations for an asset are based on the degree to which the asset is permanently affixed and not its purpose or use.

3. Elimination of Proposed Purpose or Use Test

The Treasury Department and the IRS agree with the commenters and have revised the final regulations to eliminate a purpose or use test for tangible property. Consequently, with regard to tangible property, if such property is permanently affixed to real property and will ordinarily remain affixed for an indefinite period of time, the property is generally an inherently permanent structure and thus real property for section 1031 purposes, irrespective of the purpose or use of the property or whether it contributes to the production of income. A structural component likewise is characterized as real property under the final regulations if it is integrated into an inherently permanent structure, regardless of whether the structural component contributes to the production of income. Accordingly, under the final regulations, items of machinery and equipment are characterized as real property if they comprise an inherently permanent structure, a structural component, or are real property under the State or local law test.

The Treasury Department and the IRS received no comments regarding the application of the proposed purpose or use test to real property classifications of intangible property. However, the Treasury Department and the IRS have determined that many of the comments pertaining to the purpose or use test with regard to tangible property equally apply to classifications of intangible property. As a result, under the final regulations, whether intangible property produces or contributes to the production of income other than consideration for the use or occupancy of space is not considered in determining whether intangible property is real property for section 1031 purposes. However, the purpose of the intangible property remains relevant to the real property determination.

C. Revisions to the Definition of Inherently Permanent Structure

Proposed § 1.1031(a)–3(a)(2)(ii)(A) defines the term ''inherently permanent structures'' to mean ''any building or other structure that is a distinct asset (within the meaning of [proposed § 1.1031(a)–3(a)(4)]) and is permanently affixed to real property and that will ordinarily remain affixed for an indefinite period of time.'' One commenter highlighted that the proposed regulations do not define the phrases ''permanently affixed'' or ''indefinite period of time'' for purposes of defining ''inherently permanent structure,'' other than providing that affixation to real property may be accomplished by weight alone. See proposed § 1.1031(a)–3(a)(2)(ii)(C). The commenter noted that § 1.856–10(d)(2)(i) provides that, ''[i]f the affixation is reasonably expected to last indefinitely based on all the facts and circumstances, the affixation is considered permanent.'' As a result, the commenter recommended that the final regulations clarify the meaning of these terms, including by adding the above-quoted language in § 1.856–10 to explain the phrase ''permanently affixed.''

The Treasury Department and the IRS agree with the commenter's suggestion to incorporate the language provided in § 1.856–10(d)(2)(i) to provide additional clarity regarding the meaning of ''permanently affixed'' and have revised the final regulations accordingly.

D. Comments Regarding Offshore Platforms and Pipelines, and Related Example

Proposed § 1.1031(a)–3(a)(2)(ii)(C) specifically lists offshore drilling platforms and oil and gas pipelines as inherently permanent structures, and therefore such property is defined as real property. The proposed regulations also provide an example addressing a pipeline transmission system comprised of underground pipelines, isolation valves and vents, pressure control and relief valves, meters, and compressors. See proposed § 1.1031(a)–3(b)(10) (Example 10). Example 10 concludes that the meters and compressors are not real property because (i) they are not time consuming and expensive to install and remove from the pipelines, (ii) they are not designed specifically for the particular pipelines for which they are a part, and (iii) their removal does not cause damage to the asset or the pipelines if removed. Based on the same analysis, Example 10 concludes that isolation valves and vents, and pressure control and relief valves are real property for section 1031 purposes.

One commenter suggested that the final regulations should remove the adjective ''drilling'' from ''offshore drilling platform'' as listed as an inherently permanent structure in proposed § 1.1031(a)–3(a)(2)(ii)(C). For support, the commenter stated that an

offshore platform used for production is structurally similar to an offshore platform used for drilling, and therefore the term should be appropriately broadened. As so modified, the term ''offshore platform'' would cover both offshore drilling platforms and offshore production platforms.

The commenter also provided additional recommendations regarding assets used in an oil and gas business. For example, the commenter suggested that the final regulations should explicitly provide that underground and above-ground pipelines are real property for section 1031 purposes. The commenter recommended that the final regulations characterize meters and compressors as real property. In contending that Example 10 provided an incorrect conclusion, the commenter explained that meters and compressors generally require substantial amounts of time and money to prepare, construct, and place in service due to unique circumstances affecting individual pipelines.

The Treasury Department and the IRS have clarified the final regulations based on the commenter's recommendations. As an initial matter, the final regulations delete ''drilling'' from the term ''offshore drilling platform,'' as listed in proposed § 1.1031(a)–3(a)(2)(ii)(C). The Treasury Department and the IRS agree that an offshore platform used for production likewise should be characterized as an inherently permanent structure because such property is structurally similar to an offshore platform used for drilling.

In addition, the final regulations contain a revised version of Example 10, renumbered as Example 9, to clarify the analysis and conclusions in the proposed example. With regard to an above-ground pipeline, an oil and gas pipeline is listed property in proposed § 1.1031(a)–3(a)(2)(ii)(C) and is therefore real property, regardless of whether above or below ground. Whether particular meters or compressors are real property must be determined by their unique facts and circumstances. If under different circumstances the meters or compressors described in proposed Example 10, now Example 9, required substantial amounts of time and money to prepare, construct, and place in service due to unique circumstances affecting individual pipelines, the components would be real property for section 1031 purposes. Example 9 in the final regulations illustrates these rules.

E. Requests To List Additional Tangible Assets as Real Property

1. Installed Appliances

One commenter requested that the final regulations expressly list as real property installed appliances (also referred to as ''appliances in place''), including refrigerators, stoves, dishwashers, and microwave ovens. The commenter explained that, in certain regions of the United States, residential real property generally is sold with the appliances in place as part of the sale. The commenter further stated that, in many like-kind exchanges of one-family rental properties, sellers (i) consider the appliances, furniture, and electrical fixtures remaining in the property to be part of the real property transaction, and (ii) count such items of property towards the amount of replacement property that must be acquired to avoid gain recognition under section 1031.

2. Sheds and Carports

One commenter recommended adding sheds and carports to the list of assets that are expressly included as buildings in proposed § 1.1031(a)–3(a)(2)(ii)(B). The commenter contended that such structures generally take the form of buildings and, therefore, a specific listing as a building under the final regulations would increase certainty regarding exchanges involving such assets.

3. Wi-Fi Systems

Another commenter suggested that proposed § 1.1031(a)–3(a)(2)(iii)(A) be revised to specifically list as structural components Wi-Fi systems, distributed antenna systems, and other integrated systems that may be installed in buildings to transmit and receive wireless signals and cellular service. The commenter asserted that such integrated systems are installed in buildings and inherently permanent structures, and often are as essential to the use of buildings as heating and electricity. Additionally, the commenter emphasized that such integrated systems generally require that the taxpayer hold a real property interest in conjunction with its installation of the system, and therefore should satisfy the definition of a structural component under the proposed regulations.

4. Trade Fixtures

One commenter recommended that ''trade fixtures'' be expressly listed as real property under the final regulations. The commenter noted that such items are semi-permanently affixed to real property and perform or support the performance of functions (including manufacturing, cooking, and decorative lighting) unrelated to basic building functions. Additionally, the commenter asserted that trade fixtures have historically been treated as real property for State law purposes, except in instances in which there is a plan to remove or relocate them to a different property.

5. Final Regulations Do Not Specifically List the Requested Items as Real Property

After consideration of the commenters' recommendations, the Treasury Department and the IRS have determined that the final regulations should not specifically list any of these suggested assets as real property for purposes of section 1031. The final regulations are intended to provide tests under which taxpayers can evaluate the particular facts and circumstances of the property in question to determine with certainty whether particular property is characterized as real or personal property. To limit complexity of the final regulations, the characterization of the above-listed items in this part II.E is most appropriately determined based on the application of the State and local law test or the various factors in the final regulations.

Specifically, with regard to installed appliances, whether a seller considers an item transferred with real property to be part of the real property transaction is not a relevant factor in determining whether the item is real property for section 1031 purposes. Movable items, such as furniture, are personal property irrespective of the terms of the sales contract for the real property that is the subject of the sale. Those items, however, may be incidental personal property that, under the final regulations, is disregarded in determining whether a taxpayer's rights to receive, pledge, borrow, or otherwise obtain the benefits of money or non-like-kind property held by a qualified intermediary are expressly limited as provided in § 1.1031(k)–1(g)(6).

F. Requested Clarifications Regarding Carpeting and Wiring

One commenter requested clarification regarding whether carpeting in an office building, or other real property held for productive use in a trade or business or for investment, is considered real property or personal property under the final regulations. Another commenter inquired whether wires installed within the walls of an office building are real property for section 1031 purposes if the wires were installed specifically for computer workstations that produce income for

the business. The commenter acknowledged that the proposed regulations provide that wiring is a structural component, and therefore real property for purposes of section 1031, provided the wiring is a constituent part of, and integrated into, an inherently permanent structure.

The Treasury Department and the IRS appreciate the commenters' requests for clarification regarding the qualification of carpeting and wiring as inherently permanent structures or structural components. However, such qualification would be dependent upon a facts-and-circumstances analysis unique to the specific carpeting or wiring, as well as the classification of such items under applicable State or local law. As a result, the final regulations do not adopt the commenters' suggestions, but instruct taxpayers to apply the State and local law test or the various factors in the final regulations.

G. Requests To List Additional Intangible Assets as Real Property

1. Stock in a Cooperative Housing Corporation

The proposed regulations provide that an interest in real property, including fee ownership, co-ownership, a leasehold, an option to acquire real property, an easement, or a similar interest, is real property for purposes of section 1031. See proposed § 1.1031(a)–3(a)(1). One commenter suggested that this list of items be revised to include stock held by a person as a tenant-stockholder in a cooperative housing corporation. The commenter noted that the term ''interests in real property'' for purposes of regulations regarding real estate investment trusts (REITs) includes stock held by a person as a tenant-stockholder in a cooperative housing corporation. See § 1.856–3(c).

2. Development Rights

One commenter requested that rights to develop land be expressly listed as real property in final § 1.1031(a)–3(a)(1). For support, the commenter emphasized that the IRS has published a private letter ruling that an exchange of a fee interest in real estate for development rights in real estate qualified as a like-kind exchange under section 1031. Accordingly, the commenter concluded that development rights should be specifically listed as real property in the final regulations.

3. Final Regulations Expressly List the Requested Items as Real Property

The Treasury Department and the IRS agree with the commenters' recommendations regarding stock in a cooperative housing corporation and land development rights. The intangible assets described in this part II.G have historically been characterized as real property. Accordingly, the final regulations have been revised to expressly list those intangible assets.

4. Licenses and Permits

Under the proposed regulations, a license, permit, or other similar right that is solely for the use, enjoyment, or occupation of land or an inherently permanent structure, and that is in the nature of a leasehold or easement, generally is an interest in real property under section 1031. See proposed § 1.1031(a)–3(a)(5)(ii). One commenter contended that this language is too restrictive because it addresses only leaseholds and easements.

In response to this comment, the final regulations provide that a license, permit, or other similar right that is solely for the use, enjoyment, or occupation of land or an inherently permanent structure and that is in the nature of a leasehold, an easement, or a similar right generally is an interest in real property and thus is real property under section 1031.

H. Requested Clarifications Regarding Easements and Leaseholds

Proposed § 1.1031(a)–3(a)(5)(ii) provides that a ''license, permit, or other similar right that is solely for the use, enjoyment, or occupation of land or an inherently permanent structure and that is in the nature of a leasehold or easement generally is an interest in real property.'' One commenter requested that final § 1.1031(a)–3(a)(5)(ii) add the word ''perpetual'' or ''permanent'' before ''easement'' to communicate that an easement must have a term exceeding 30 years as of the date of the exchange to be consistent with § 1.1031(a)–1(c). Under that regulation, examples of exchanges of real property of a like kind include an exchange of a leasehold interest in a fee with a term of 30 years or more to run for real estate.

On this aspect of easements and leaseholds, however, the comments received were not uniform. For example, another commenter requested that final § 1.1031(a)–3(a)(5)(ii) specify that leaseholds or easements of any duration are an interest in real property under section 1031. As a conforming revision, the commenter also recommended that the final regulations remove the reference in § 1.1031(a)–1(c) to leaseholds with 30 years or more to run to provide parity among all interests in real property eligible for like-kind exchanges under section 1031. In addition, a separate commenter recommended that the final regulations clarify whether a leasehold interest in real property must have, as of the date of the exchange, a remaining term of at least 30 years or more in order to qualify as an interest in real property.

The Treasury Department and the IRS note, as an initial matter, that the proposed and final regulations address solely the qualification of an asset as real property for section 1031 purposes, and do not specifically address whether an exchange is like kind. Duration of an easement or a leasehold is not relevant in determining whether the easement or leasehold is real property under § 1.1031(a)–3(a)(5), and therefore, proposed § 1.1031(a)–3(a)(5)(ii) did not include a reference to duration. The commenters, however, correctly note that duration may be relevant under § 1.1031(a)–1(c) for purposes of determining whether an exchange of an easement or leasehold for real property would qualify as like kind. Because like-kind determinations exceed the scope of the final regulations, the commenters' suggestions and requests for clarification regarding like-kind determinations are not incorporated into these final regulations.

I. Applicability of Distinct Asset Test to Three-Property Rule in § 1.1031(k)–1(c)(4)(i)(A)

The proposed regulations provide that, in general, each distinct asset is analyzed separately from each other distinct asset in determining whether a distinct asset is real property for section 1031 purposes. One commenter requested that the final regulations clarify that this distinct asset rule does not apply for purposes of § 1.1031(k)–1(c)(4)(i)(A), which generally limits a taxpayer to the identification of three replacement properties (three-property rule). In response to the comment, the Treasury Department and the IRS have added language to the definition of distinct asset in § 1.1031(a)–3(a)(4) to clarify that the distinct asset rule applies only for purposes of determining whether property is real property for section 1031 purposes and does not affect the application of the three-property rule.

III. Incidental Property Rule

A. Approach of the Proposed Regulations

Section 1.1031(k)–1(g)(7)(iii) of the proposed regulations addresses the receipt of personal property that is incidental to the taxpayer's replacement real property in an exchange (incidental property rule). The incidental property

rule provides that, for exchanges involving a qualified intermediary, personal property that is incidental to replacement real property (incidental personal property) is disregarded in determining whether a taxpayer's rights to receive, pledge, borrow, or otherwise obtain the benefits of money or non-like-kind property held by the qualified intermediary are expressly limited as provided in § 1.1031(k)–1(g)(6). However, as personal property, incidental personal property is non-like-kind property that generally results in gain recognition under section 1031(b) on the exchange.

Personal property is incidental to real property acquired in an exchange if (i) in standard commercial transactions, the personal property is typically transferred together with the real property, and (ii) the aggregate fair market value of the incidental personal property transferred with the real property does not exceed 15 percent of the aggregate fair market value of the replacement real property (15-percent limitation).

B. Calculation of 15-Percent Limitation

The Treasury Department and the IRS received several comments recommending a change to the calculation of the amount of incidental property that a taxpayer may acquire and still meet the requirements of the incidental property rule. For example, commenters recommended that the value of incidental property under the final regulations be permitted to equal up to 15 percent of the total fair market value of the replacement real property, as well as the incidental property. For support, these commenters highlighted that their suggested 15-percent calculation is consistent with sections 856(d)(1)(C) and 856(c)(9)(A)(ii) of the Code pertaining to REITs. In addition, a commenter suggested that final § 1.1031(k)–1(g)(7)(iii) should permit the aggregate fair market value of the incidental personal property to equal up to 20 percent of the aggregate fair market value of the replacement real property.

The final regulations do not adopt these comments. As explained in part II of the Explanation of Provisions section of the preamble to the proposed regulations, the proposed incidental property rule is ''based on the existing rule in § 1.1031(k)–1(c)(5), which provides that certain incidental property is ignored in determining whether a taxpayer has properly identified replacement property under section 1031(a)(3)(A) and § 1.1031(k)–1(c).'' 85 FR 35839. In addition, the Treasury Department has determined that a limitation in excess of 15 percent ''might induce taxpayers to bundle more personal property with their exchanged property,'' which ''would lead to increased amounts of personal property exchanged with real property under section 1031 and effectively unlock a class of personal property that would no longer be 'incidental' to the real property.'' 85 FR 35840. Consequently, the Treasury Department and the IRS continue to believe that the proposed 15-percent limitation, and its calculation, are ''responsive to ordinary-course exchanges that often commingle personal property and real property as part of the aggregate exchanged property.'' Id.

C. Requests To Identify Incidental Property Rule as a Safe Harbor

Commenters requested that the incidental property rule be specifically identified in the final regulations as a safe harbor. One commenter expressed concern that, unless identified as a safe harbor, the incidental property rule may be interpreted as a bright-line rule under which acquisitions of personal property valued in excess of 15 percent of the real property will cause the exchange to fail, and the transfer of relinquished property to be fully taxable. Additionally, a separate commenter requested that the final regulations clarify that incidental property may include intangible property such as goodwill.

The final regulations do not adopt the request that the incidental property rule be identified as a safe harbor. The items in current § 1.1031(k)–1(g)(1) through (5) consist of safe harbors that help taxpayers comply with other rules in § 1.1031(k)–1, and § 1.1031(k)–1(g)(7)(i) and (ii) are items that are disregarded in determining whether one of the existing safe harbors ceases to apply. The incidental property rule adds an additional item to § 1.1031(k)–1(g)(7) that is disregarded in determining whether one of the existing safe harbors ceases to apply. Identifying the incidental property rule as a safe harbor would thus be confusing because it is an item that is disregarded in determining if an existing safe harbor applies. Therefore, the incidental property rule operates as part of an existing safe harbor. Consequently, acquisitions of personal property valued in excess of 15 percent of the replacement real property are not disregarded in determining if one of the safe harbors in § 1.1031(k)–1(g)(3) through (5) ceases to apply and whether the taxpayer's rights to receive, pledge, borrow, or otherwise obtain the benefits of money or non-like-kind property are expressly limited as provided in § 1.1031(k)–1(g)(6), but will not automatically cause the exchange to fail section 1031 and the transfer of relinquished property to be treated as a sale or taxable exchange.

Further, the incidental property rule applies to non-real property, regardless of whether tangible or intangible. No change to the regulations is required to accommodate this suggestion.

D. Application of Section 1031(b) to Receipt of Incidental Personal Property

Several commenters recommended that the final incidental property rule provide that a taxpayer's receipt of personal property incidental to the real property received in a like-kind exchange be treated as the receipt of real property, and thus not give rise to recognized gain under section 1031(b). Under section 1031(b), a taxpayer must recognize gain on a section 1031 exchange to the extent of money or non-like-kind property the taxpayer receives in the exchange. Similarly, one commenter suggested that, if the final regulations require recognition of gain on the receipt of incidental personal property, the final regulations should not include the incidental property rule. That commenter contended that inclusion of the incidental property rule in the final regulations will result in some taxpayers misinterpreting the rule by treating incidental personal property in the same manner as real property for purposes of the nonrecognition of gain or loss under section 1031.

The final regulations do not adopt the commenters' recommendations. As amended by the TCJA, section 1031(a) is limited to exchanges of real property. However, the TCJA did not amend section 1031(b), which provides that a taxpayer must recognize gain on an exchange to the extent of money and non-like-kind property received in the exchange. Personal property received in a like-kind exchange of real property is non-like-kind property received in the exchange. Consequently, under section 1031(b), gain generally must be recognized to the extent of the personal property received in the exchange.

The final regulations revise proposed § 1.1031(k)–1(g)(7)(iii)(B) slightly to improve readability; the revision does not change the meaning of proposed § 1.1031(k)–1(g)(7)(iii)(B).

The final regulations include the incidental property rule to provide assurance to taxpayers that a qualified intermediary's use of exchange proceeds to acquire incidental personal property will not cause the taxpayer to fail to meet the requirements of § 1.1031(k)–1(g)(6)(i), and thus the requirements of section 1031. As explained in the preamble to the proposed regulations,

the incidental property rule was proposed to respond to concerns that a taxpayer would be considered to be in constructive receipt of all of the exchange funds held by the qualified intermediary if the taxpayer is able to direct the qualified intermediary to use those funds to acquire property that is not of a like kind to the taxpayer's relinquished property. See generally part II of the Explanation of Provisions section in the preamble to the proposed regulations. The incidental property rule is intended to help taxpayers comply with the requirements of section 1031, particularly the prohibition on a taxpayer's ability to actually or constructively receive the proceeds from the transfer of relinquished property before receiving like-kind replacement property.

One commenter recommended that the final regulations include language specifically providing that the receipt of incidental personal property in a section 1031 exchange results in taxable gain to the taxpayer. The final regulations adopt this recommendation and add language in § 1.1031(k)–1(g)(7)(iii) to clarify this point.

E. Request That 15-Percent Limitation Not Be Applied on a Property-by-Property Basis

One commenter recommended that the final regulations clarify that the 15-percent limitation for the incidental property rule is not applied on a property-by-property basis. For example, assume a taxpayer acquires an office building (Building 1) with office furniture, and a second office building (Building 2) with no personal property. The commenter requested that the final regulations confirm that the taxpayer does not exceed the 15-percent limitation if the value of the furniture is 15 percent or less of the total value of Building 1 and Building 2, even if the value of the furniture exceeds 15 percent of the value of just Building 1.

The Treasury Department and the IRS agree with the commenter's recommendation. Accordingly, the final regulations include language to clarify that the 15-percent limitation is calculated by comparing the value of all of the incidental properties to the value of all of the replacement real properties acquired in the same exchange.

F. Suggested Language Changes to Incidental Property Rule

One commenter recommended a series of language modifications to the incidental property rule in the proposed § 1.1031(k)–1(g)(7)(iii). For example, the commenter recommended that the rule for determining whether personal property is incidental to real property acquired in an exchange not reference the term ''commercial transaction.'' For support, the commenter asserted that the term might be interpreted to include only contracts involving transfers of non-residential property such as commercial real estate and not residential rental property. In addition, the commenter suggested that, in the final regulations, the language ''the personal property is typically transferred together with the real property'' be replaced with ''the personal property is typically listed in the contract and transferred with the real property.''

The final regulations do not adopt these suggested modifications because the Treasury Department and the IRS have determined that proposed § 1.1031(k)–1(g)(7)(iii) provides clear guidance for determining whether personal property is incidental to real property acquired in an exchange. In particular, the term ''commercial transactions'' refers to transactions involving business or investment property rather than personal-use property. Accordingly, the term ''commercial'' describes the type of transaction, not the type of property. Therefore, a commercial transaction may involve either residential or non-residential property.

The final regulations also do not adopt the commenter's recommendation that the language ''the personal property is typically transferred together with the real property'' be replaced with ''the personal property is typically listed in the contract and transferred with the real property.'' Generally, if personal property is transferred as part of a transfer of real property, the personal property would be listed in the contract relating to the transfer. However, if a taxpayer lists the personal property in a contract separate from the contract addressing the transfer of real property, listing the personal property in a separate contract generally will not prevent the taxpayer from using the incidental property rule.

G. Request To Apply Incidental Property Rule Retroactively

A commenter also requested that, under the final regulations, the incidental property rule apply retroactively to exchanges after either (i) the 1984 enactment of the deferred exchange rules in section 1031(a)(3) or (ii) the 1991 effective date of the § 1.1031(k)–1 deferred exchange final regulations. The commenter observed that the concerns that led to the inclusion of the incidental property rule in the proposed regulations, which include directing a qualified intermediary to use exchange proceeds to acquire non-like-kind property, also existed for pre-TCJA exchanges under section 1031. Thus, the commenter suggested that the incidental property rule apply to pre-TCJA exchanges.

Prior to enactment of the TCJA, personal property was eligible for like-kind exchange treatment. Therefore, a rule disregarding the receipt of incidental personal property in determining whether a taxpayer was in constructive receipt of non-like-kind property prior to enactment of the TCJA would function in a very different way than it does post-TCJA. Accordingly, these final regulations do not adopt this suggestion.

H. Requested Clarifications Regarding Receipt of Personal Property or Escrow Funds

Commenters requested clarification regarding the application of the incidental property rule to cash placed in escrow to pay transactional and other items in a real estate transfer. The Treasury Department and the IRS note that a taxpayer's receipt of escrowed funds that the taxpayer placed in escrow for transactional-type items is not a receipt of incidental personal property. Therefore, the final regulations do not revise the incidental property rule in response to the commenters' request. A commenter also requested guidance regarding situations in which an exchanging taxpayer acquires a substantial amount of personal property due to unforeseen circumstances. The final regulations do not address this specific situation. The 15-percent limitation is not a bright-line test for determining whether a transaction fails to meet the requirements of an exchange under section 1031. All of the facts and circumstances of the taxpayer's situation are considered in determining if the exchange meets the requirements of section 1031.

IV. Comments That Exceed the Scope of the Final Regulations

A. Application of Section 453 of the Code To Gain on a Transfer of Personal Property

A commenter recommended that the final regulations provide clarification regarding the application of section 453 to certain like-kind exchanges. Specifically, the commenter requested guidance about the timing of gain recognition when (i) real property is exchanged for both like-kind real property and non-like-kind personal property incidental to the real property, and (ii) the exchange is not completed

until the taxable year succeeding the taxable year of the transfer of the relinquished property. The commenter requested that the final regulations address whether the gain on the receipt of the personal property is recognized in the first or the second taxable year (Tax Year 1 and Tax Year 2, respectively) if the like-kind exchange straddles two taxable years.

The commenter also requested guidance regarding a situation involving a taxpayer who (i) has a *bona fide* intent to execute a section 1031 exchange, (ii) transfers relinquished real property and incidental personal property in Tax Year 1, and (iii) fails to acquire replacement property by the 180th day after the transfer of the relinquished property, which is in Tax Year 2. Specifically, the commenter recommends that the final regulations address whether the gain on the transfer of the personal property is recognized in Tax Year 1 or Tax Year 2.

The Treasury Department and the IRS appreciate the commenter's questions but have determined the commenter's requested guidance exceeds the scope of the final regulations. The issues raised by the commenter relate to the application of current § 1.1031(k)–1(j)(2), which addresses the application of the installment method of accounting in section 453 to like-kind exchanges involving the receipt of non-like-kind property that straddles two taxable years, or that would have straddled two taxable years if successfully completed. The scope of the final regulations is limited to the definition of real property under section 1031 and to incidental property received in a section 1031 exchange. Accordingly, the final regulations do not address the issues relating to the timing of gain recognition raised by the commenter.

B. Application of Current § 1.1031(j)–1 to Post-TCJA Exchanges

Several commenters inquired about the application of current § 1.1031(j)–1 to exchanges of multiple properties following the enactment of the TCJA. Section 1.1031(j)–1 provides an exception to the general rule that section 1031 requires a property-by-property comparison for computing the gain recognized and basis of property received in a like-kind exchange. Section 1.1031(j)–1 applies when there is more than one exchange group created, as described in § 1.1031(j)–1(b)(2)(i), or, if there is only one exchange group, there is more than one property transferred or received within the exchange group. Under § 1.1031(j)–1, the amount of gain recognized and the basis of the properties received by a taxpayer are computed after separating the properties transferred and received by the taxpayer in the exchange into exchange groups, in accordance with the rules in § 1.1031(j)–1(b)(3) and (c), respectively. In addition, under § 1.1031(j)–1(b)(2)(ii), all liabilities assumed by a taxpayer as part of an exchange to which § 1.1031(j)–1 applies are offset against all liabilities of which the taxpayer is relieved as part of the exchange.

One commenter asked whether § 1.1031(j)–1 applies to a post-TCJA exchange of real property and personal property for other real property and personal property. Under section 1031 as in effect before the TCJA amendments, § 1.1031(j)–1 would have applied to this exchange if the relinquished real property was of a like kind to the replacement real property, and the relinquished personal property was of a like kind to the replacement personal property. Other commenters requested the Treasury Department and the IRS to conclude that § 1.1031(j)–1 will continue to apply in this situation so that taxpayers will not have to carry out a property-by-property comparison for computing gain on the exchange.

Another commenter inquired about the application of § 1.1031(j)–1 to exchanges of both qualifying real property and non-qualifying property that involve indebtedness encumbering both types of properties. Specifically, the commenter asked whether the full amount of the indebtedness assumed by the taxpayer would offset the full amount of the indebtedness liabilities of which the taxpayer is relieved as part of the exchange, even if a portion of that indebtedness relates to the personal property in the exchange.

The Treasury Department and the IRS appreciate the issues raised by these commenters but note that the application of § 1.1031(j)–1 to transactions to which the TCJA applies exceeds the scope of the final regulations. Therefore, the final regulations do not address these comments. The Treasury Department and the IRS, however, continue to consider potential future guidance on issues relating to § 1.1031(j)–1.

C. Application of Revenue Rulings 2003–56 and 2004–86

One commenter suggested that Rev. Rul. 2003–56, 2003–23 I.R.B. 985, likely needs to be modified to address post-TCJA exchanges involving both real and personal property. The commenter also questioned whether Rev. Rul. 2004–86, 2004–33 I.R.B. 191, needs to be updated to address the TCJA changes to section 1031.

Rev. Rul. 2003–56 addresses the consequences under section 752 of the Code and § 1.704–2(d) of a section 1031 like-kind exchange that straddles two taxable years and involves relinquished and replacement property subject to a liability. The revenue ruling addresses whether the liabilities are netted and which taxable year the net change in a partner's share of partnership liability is taken into account.

Rev. Rul. 2004–86 addresses whether an interest in a Delaware statutory trust (DST) is treated as an interest in the real property owned by the DST, and whether a taxpayer may exchange real property for an interest in a DST in a transaction that qualifies for nonrecognition of gain under section 1031. The revenue ruling examines the grantor trust rules of sections 671 and 677 of the Code and the entity-classification rules in section 7701 of the Code and the section 7701 regulations. Rev. Rul. 2004–86 concludes that, under the facts of the ruling, including the DST agreement, the exchange qualifies for nonrecognition under section 1031.

The Treasury Department and the IRS appreciate these helpful comments but have determined that they exceed the scope of the final regulations. That scope is limited to the definition of real property under section 1031 and to incidental property received in a section 1031 exchange. Both Rev. Rul. 2003–56 and Rev. Rul. 2004–86 address other issues related to the application of section 1031.

With regard to Rev. Rul. 2004–86, nothing in the proposed regulations or the TCJA is contrary to the view that a transfer of an interest in a DST, if a grantor trust, is treated as the transfer of the underlying property held by the DST. The Treasury Department and the IRS, however, will continue to review existing guidance concerning section 1031 like-kind exchanges to determine the effect of the TCJA on that guidance.

D. Computation Error in Examples Contained in § 1.1031(k)–1(d)(2)

A commenter highlighted that examples in § 1.1031(k)–1(d)(2) include a computation error. For example, the sum of $187,500 and $87,500 is incorrectly provided as $250,000. Although, the proposed regulations do not address the rules in § 1.1031(k)–1(d)(2), this Treasury decision corrects the scrivener's error identified by the commenter by replacing ''$87,500'' with ''$62,500'' each place it appears therein.

E. Interaction of Bonus Depreciation Rules With Section 1031

One commenter discussed the interaction between the additional first year depreciation deduction rules in section 168 of the Code, commonly referred to as bonus depreciation, and the like-kind exchange rules in section 1031, as amended by the TCJA. The commenter pointed out that there may be an adverse timing difference between (i) when gain is recognized on the transfer of real property that includes the transfer of personal property, and (ii) when a taxpayer is allowed a bonus depreciation deduction for the acquisition of replacement real property and personal property subject to bonus depreciation. The commenter also asserted that when the 100-percent bonus depreciation rules expire after 2022, the gain associated with a section 1031 exchange involving real estate including personal property will be larger than the gain intended by Congress.

These comments, while helpful, exceed the scope of the final regulations. Accordingly, the final regulations do not include the guidance requested by the commenter. However, the Treasury Department and the IRS will consider the interaction between the bonus depreciation rules under section 168 and the like-kind exchange rules under section 1031.

V. Correction to Preamble of Proposed Regulations Regarding Kind or Class of Property

One commenter noted that the background section of the preamble to the proposed regulations provides the following: ''Real property of one kind or class may not, under section 1031, be exchanged for real property of a different kind or class.'' Proposed regulations, Background, part III. The commenter correctly pointed out that this sentence is inaccurate because distinguishing between properties of a different class is relevant to personal property and whether, under section 1031 prior to enactment of the TCJA, personal properties were of like kind, not whether the properties were real property. Consequently, this sentence is deleted from part III of the Background of the preamble to the final regulations.

Statement of Availability of IRS Documents

The IRS guidance cited in this preamble is published in the Internal Revenue Bulletin (or Cumulative Bulletin) and is available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

Effective/Applicability Date

These final regulations apply to exchanges beginning after December 2, 2020. A taxpayer may rely on the proposed regulations (REG–117589–18) published in the **Federal Register** on June 12, 2020 (85 FR 35835), if followed consistently and in their entirety, for exchanges of real property beginning after December 31, 2017, and before December 2, 2020.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Executive Orders 12866, 13563, and 13771 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including (i) potential economic, environmental, and public health and safety effects, (ii) potential distributive impacts, and (iii) equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

These regulations have been designated as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) (MOA) between the Treasury Department and the Office of Management and Budget (OMB) regarding review of tax regulations. The Office of Information and Regulatory Affairs (OIRA) has designated these final regulations as economically significant under section 1(c) of the MOA. Accordingly, the OMB has reviewed these final regulations.

A. Background

1. Like-Kind Exchange

Prior to the amendment of section 1031 by the TCJA, certain exchanges of personal, intangible, or real property held for use in a trade or business or for investment qualified for nonrecognition under section 1031. Section 13303 of the TCJA generally limits the application of like-kind exchange treatment to exchanges of real property after December 31, 2017, subject to a transition rule applicable to exchanges not completed by January 1, 2018. Specifically, section 1031 provides that no gain or loss is recognized on the exchange of real property held for productive use in a trade or business or for investment if the real property is exchanged solely for real property of a like kind that is to be held either for productive use in a trade or business or for investment.

2. Final Regulations

The final rules provide a definition of real property to distinguish it from personal property, as the TCJA limited the nonrecognition of gain or loss in the case of like-kind exchange to exchanges of real property. The legislative history to the TCJA provides that real property eligible for like-kind exchange treatment prior to the TCJA should continue to be eligible for like-kind exchange treatment. Conference Report, at 396, fn. 726. On June 12, 2020, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–117589–18) in the **Federal Register** (85 FR 35835) containing proposed regulations under section 1031 (proposed regulations). The final regulations retain the basic approach and structure of the proposed regulations, with certain revisions. In particular, the final regulations revise the definition of ''real property'' in the proposed regulations to provide that property is classified as real property for section 1031 purposes if, on the date it is transferred in an exchange, the property is real property under the law of the State or local jurisdiction in which that property is located. However, property ineligible for like-kind exchange treatment after enactment of the TCJA remains ineligible for like-kind exchange treatment after the enactment of the TCJA regardless of its classification under the laws of the State or local jurisdiction. The final regulations also revise the proposed definition of real property to eliminate, with regard to both tangible and intangible properties, any consideration of whether the particular property contributes to the production of income unrelated to the use or occupancy of space (referred to as the ''purpose or use test,'' as defined in part II.B.1 of this Summary of Comments and Explanation of Revisions).

The final regulations retain the rule relating to personal property in an exchange that is incidental to the real property exchange. Under this rule personal property is incidental to real property acquired in an exchange if, in standard commercial transactions, the personal property is typically transferred together with the real property, and the aggregate fair market value of the incidental personal property transferred with the real property does not exceed 15 percent of the aggregate fair market value of the replacement real property. This incidental property rule in the proposed

regulations is based on an existing rule in the regulations under section 1031, which provides that certain incidental property is ignored in determining whether a taxpayer has properly identified replacement property.

3. No-Action Baseline

In this analysis, the Treasury Department and the IRS assess the benefits and costs of these final regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these final regulations.

4. Economic Analysis of Final Regulations

The statutory changes made by the TCJA to section 1031 limit like-kind exchanges to real property. The final regulations provide that property is real property for purposes of section 1031 if, on the date it is transferred in an exchange, that property is classified as real property under the law of the State or local jurisdiction in which that property is located (local law test). Consequently, under the final regulations, property is classified as real property for purposes of section 1031 if the property is (i) so classified under the State and local law test, (ii) specifically listed as real property in the final regulations, or (iii) considered real property based on all the facts and circumstances under the various factors provided in the final regulations. The proposed regulations had extracted certain portions of the definition of real property from various existing regulations with the intention that they are consistent with the legislative history underlying the TCJA amendment to section 1031. *See, for example,* §§ 1.263(a)–3(b)(3) and 1.856–10 (defining the term ''real property'' to mean land and improvements to land such as buildings and other inherently permanent structures, and their structural components); § 1.263A–8(c) (providing that real property includes unsevered natural products of land such as growing crops and plants, mines wells and other natural deposits); and § 1.856–10(c) (providing, in relevant part, that the term ''land'' includes ''water and air space superjacent to land'').

The final regulations also eliminate the purpose or use test for tangible property to qualify as real property that was included in the proposed regulations. If tangible property is permanently affixed to real property and will ordinarily remain affixed for an indefinite period of time, the property is an inherently permanent structure and thus real property for section 1031 purposes, irrespective of the purpose or use of the property or whether it contributes to the production of income.

As emphasized in comments received by the Treasury Department and the IRS, the proposed regulations may have caused certain real property that qualified for like-kind exchange treatment prior to the enactment of the TCJA to no longer qualify. The final regulations more closely follow the legislative history to the TCJA amendments to section 1031. *See* Conference Report, at 396, fn. 726 (providing that Congress ''intended that real property eligible for like-kind exchange treatment under present law will continue to be eligible for like-kind exchange treatment under the [amended] provision''). The Treasury Department and the IRS have determined that using the local law test and eliminating the purpose or use test will reduce compliance costs relative to the proposed rules. As a result, taxpayers may rely on existing State and local law definitions of real property or may look to the specifically listed property or the various factors provided in the final regulations.

The Treasury Department and the IRS have determined that there is not likely to be a material difference in the quantity of tangible property that qualifies as real property eligible for like-kind exchanges under the two standards. In making this determination, the Treasury Department and the IRS observed that, for an exchange to qualify for gain-deferral treatment under section 1031, the subject property (that is, the relinquished property) not only must constitute ''real property,'' but also must be ''like kind'' with regard to the property exchanged therefore (that is, the replacement property). Like-kind determinations are made pursuant to Federal, rather than State or local, tax law. See generally § 1.1031(a)–1(b) through (d). Consequently, State and local law definitions of real property, on their own, affect only one prong of the section 1031 qualification for exchanges of property as a result of these final regulations. In the future, State and local governments could modify their tax laws to include additional assets within the definition of real property. However, the Treasury Department and the IRS cannot determine the extent to which State and local governments may take such actions. The Treasury Department and the IRS note that such actions likely would affect the tax revenue of those jurisdictions.

Moreover, the final regulations provide that property ineligible for like-kind exchange treatment prior to enactment of the TCJA remains ineligible, including real property that was excluded from the application of section 1031. This approach is consistent with Congressional intent that ''real property eligible for like-kind exchange treatment'' under the law in effect prior to enactment of the TCJA will continue to be eligible for like-kind exchange treatment after enactment of the TCJA. See Conference Report at 396, fn. 726. Prior to amendment by the TCJA, former section 1031(a)(2) explicitly excluded certain assets from the application of section 1031. Accordingly, the final regulations exclude from the definition of real property the intangible assets listed in section 1031(a)(2) prior to its amendment by the TCJA, regardless of the classification of the property under State or local law, because such property never was ''real property eligible for like-kind exchange treatment'' prior to enactment of the TCJA. Conference Report at 396, fn. 726. The final regulations may influence which intangible assets qualify as real property for like-kind exchanges relative the definition in the proposed regulations. To the extent an intangible asset derives its value from real property or an interest in real property, it is inseparable from that real property or interest in real property. Accordingly, the intangible asset does not produce or contribute to the production of income other than consideration for the use or occupancy of space, and therefore may be real property or an interest in real property under State or local law. Under the proposed regulations, the intangible asset, such as mineral extraction rights or timber cutting rights, that produces income other than for the use or occupancy of space and would not be considered real property. Under the final regulations, the mineral rights and timber cutting rights are real property if they are considered real property under State or local law.

The modification of the definition of real property in the final regulations aligns the proposed definition to more closely track the intent of Congress as described in the Conference Report. The proposed rules could have had a significant impact on the amount of intangible property that previously qualified for like-kind exchanges. For example, oil and gas firms accounted for approximately $4 billion in deferred gains in 2012. This figure can be viewed as an upper limit on the size of the taxable income that the proposed rule could have excluded from qualifying for like-kind exchanges as it includes both developed fields that would have qualified under the proposed rule and

mineral rights that may have been excluded. The proposed rule may have also affected other intangible real property such as mineral rights not associated with oil and gas properties or timber cutting rights, but these are likely small when compared to the deferred gains in the oil and gas industry.

Consistent with longstanding regulations under section 1031, in determining whether a taxpayer has actual or constructive receipt of money or other property held by a qualified intermediary, the final regulations disregard certain incidental personal property. Specifically, the final regulations disregard incidental personal property that (1) in standard commercial transactions is typically transferred together with the real property, and (2) does not exceed 15 percent of the aggregate fair market value of the replacement real property. Nonetheless, under section 1031(b), a taxpayer must recognize gain on the receipt of the incidental personal property, which is not like-kind to real property. The 15-percent limitation is responsive to ordinary-course exchanges that often commingle personal property and real property as part of the aggregate exchanged property.

With regard to a limitation on the value of incidental personal property in excess of 15 percent, the Treasury Department and the IRS have determined that a higher limit might induce taxpayers to bundle more personal property with their exchanged property. Such a result would lead to increased amounts of personal property exchanged with real property under section 1031 and effectively unlock a class of personal property that would no longer be ''incidental'' to the real property. With regard to a lower limit, the Treasury Department and the IRS have determined that the burden of accurately measuring the separate costs of comingled personal and real property would increase.

In addition, the final 15 percent incidental personal property limitation would reduce the cost of investing in real property, when compared to no exchanges for incidental personal property. Raising this limit, however, would further increase the tax incentives for investing in such property, although most taxpayers will be indifferent when exchanging incidental property, plants, and equipment with a depreciable life of 20 years or less that is eligible for 100 percent additional first year depreciation, commonly referred to as ''bonus depreciation.'' Under 100 percent bonus depreciation, gains from the sale of property can be offset by deductions for investment in other qualifying property. Qualifying property placed in service after September 27, 2017, and before January 1, 2023, qualifies for full bonus depreciation. The bonus depreciation rate is phased down 20 percent a year for property placed in service after this date. In the absence of 100 percent bonus depreciation, expanding incentives for like-kind exchange through a higher incidental personal property limitation could also distort investment decisions within and across industries leading to over-investment in like-kind properties relative to consistent treatment across properties.

As part of the economic analysis of the proposed regulations, the Treasury Department and the IRS requested comments and information that would help further inform the analysis underlying the proposed 15-percent limitation for incidental personal property. *See* part I.A.4 of the Special Analyses of the proposed regulations (85 FR 35840). No comments were received by the Treasury Department or the IRS.

The Treasury Department and the IRS have determined that these final regulations will not have meaningful effects regarding the section 1031 qualification of real property exchanges. Finally, these final regulations do not significantly affect compliance burdens as the regulations are substantially similar to existing regulations affecting like-kind exchanges for real property.

II. Paperwork Reduction Act

The collection of information in these final regulations is reflected in the collection of information for Form 8824, Like-Kind Exchanges, which has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507(c)) under control numbers 1545–0074. The number of respondents to Form 8824 for tax year 2018 is estimated at 125,000–220,000. The estimated burden for individual taxpayers filing this form is approved under OMB control number 1545–0074 and is included in the estimates shown in the instructions for their individual income tax return. The estimated burden for taxpayers who file Form 8824, which has not changed as a result of these final regulations, is shown below.

Recordkeeping	10 hr., 16 min.
Learning about the law or the form.	1 hr., 59 min.
Preparing the form	2 hr., 14 min.

Form 8824 is used by taxpayers engaging in section 1031 like-kind exchanges. Beginning after December 31, 2017, section 1031 like-kind exchange treatment applies only to exchanges of real property held for use in a trade or business or for investment, other than real property held primarily for sale. Before the law change, section 1031 also applied to certain exchanges of personal or intangible property. These final regulations provide a definition of real property for purposes of section 1031 and a rule for the receipt of personal property that is incidental to real property received in an exchange and makes conforming changes to the regulations. The law change reflected in the final regulations will result in fewer taxpayers engaging in section 1031 like-kind exchanges. This decrease in burden will be reflected in the updated burden estimates for the Form 8824. The requirement to maintain records to substantiate information on the Form 8824 is already contained in the burden associated with the control numbers for those forms and remains unchanged. For purposes of the Paperwork Reduction Act, no burden estimates specific to the final regulations are currently available. The Treasury Department has not estimated the burden, including that of any new information collections, related to the requirements under the final regulations. Those estimates would capture both changes made by the TCJA and those that arise out of discretionary authority exercised in the final regulations.

The current status of the Paperwork Reduction Act submissions related to section 1031 is provided in the following table. The section 1031 provisions are included in aggregated burden estimates for OMB control number 1545–0074, which represents a total estimated burden time, including all related forms and schedules, of 1.784 billion hours and total estimated monetized costs of $31.764 billion ($2017). The burden estimates provided in the OMB control numbers below are aggregate amounts that relate to the entire package of forms associated with the OMB control number and will in the future include but not isolate the estimated burden of only the section 1031 requirements. These numbers are therefore unrelated to the future calculations needed to assess the burden imposed by the final regulations. The Treasury Department and IRS urge readers to recognize that these numbers are duplicates and to guard against over-counting the burden that tax provisions imposed prior to the TCJA. The Treasury Department and the IRS request comments on all aspects of

information collection burdens related to the final regulations. In addition, when available, drafts of IRS forms are posted for comment at *www.irs.gov/draftforms.*

Form 8824	Individual (NEW Model) 1545–0074.	Sixty-day notice published in the **Federal Register** on 10/30/20 (85 FR 68956). Public Comment period closes on 12/29/20.

Link: *https://www.federalregister.gov/documents/2020/10/30/2020-24139/proposed-extension-of-information-collection-request-submitted-for-public-comment-comment-request.*

Form 8824 is also used by members of the executive branch of the Federal Government and judicial officers of the Federal Government to elect to defer gain under section 1043 on certain sales of property due to potential conflicts of interest arising from their status as government officials. These final regulations do not address or affect the deferral of gain on sales under section 1043.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and return information are confidential, as required by 26 U.S.C. 6103.

III. Regulatory Flexibility Act

It is hereby certified that these final regulations will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act (5 U.S.C. chapter 6).

These final regulations update existing regulations under section 1031 to reflect statutory changes made to section 1031 by the TCJA. Section 1031 provides that a taxpayer exchanging investment property or property held for productive use in a trade or business for other investment or trade or business property recognizes gain only to the extent of money or non-like-kind property received in the exchange, and recognizes no loss on the exchange. Under the TCJA amendments to section 1031, for years after 2017, section 1031 applies only to exchanges of real property and no longer applies to exchanges of personal property and certain intangible property. The final regulations provide a definition of real property to be used in determining whether a taxpayer has met the requirements of section 1031. In so doing, the final regulations follow the legislative history underlying the TCJA amendment to section 1031 providing that real property eligible for like-kind exchange treatment under pre-TCJA law continues to be eligible for like-kind exchange treatment in years beginning after 2017.

Consequently, the final regulations use a State or local law test and certain aspects from existing regulatory definitions of real property in a manner consistent with the legislative history underlying the TCJA amendment to section 1031 requiring that the definition of real property remain the same both before and after enactment of the TCJA. Taxpayers already are familiar with these rules, which provide that real property includes land, improvements to land, unsevered natural products of land, and water and air space superjacent to land. In addition, the final regulations provide a rule addressing a taxpayer's receipt of personal property that is incidental to the real property the taxpayer receives in the exchange that is based on an existing rule in § 1.1031(k)–1.

Individuals and business entities that own investment real property or real property held for productive use in a trade or business may engage in a section 1031 exchange. The provisions of section 1031 apply in the same manner to all taxpayers, so the effect of the final regulations is the same for taxpayers that are small entities and taxpayers that are not small entities. The small entities potentially impacted by these regulations are businesses organized as corporations (including S corporations), partnerships, and individuals that file a Form 1040 Schedule C for their respective trades or businesses or Form 1040 Schedule E for their rental real estate.

The number of small entities potentially affected by these final regulations is unknown but likely substantial because like-kind exchanges are entered into by entities of all sizes. Although a substantial number of small entities is potentially affected by these final regulations, the Treasury Department and the IRS have concluded that the final regulations will not have a significant economic impact on a substantial number of small entities because the costs to comply with these final regulations are not significant. This is because for taxpayers still able to engage in section 1031 exchanges, there are no additional forms they are required to file, and there is no new recordkeeping required, to comply with section 1031 as amended by the TCJA and these final regulations other than the time to read and understand these regulations. Thus, taxpayers that engage in like-kind exchanges of real property in 2018 and later years will not have any additional burden as compared to taxpayers engaging in like-kind exchanges in years before 2018. Accordingly, the Secretary certifies that these final regulations will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f), the notice of proposed rulemaking preceding this final regulation was submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business (85 FR 35835). No comments on the notice were received from the Chief Counsel for the Office of Advocacy of the Small Business Administration.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This rule does not include any mandate that may result in expenditures by State, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the

consultation and funding requirements of section 6 of the Executive Order. This rule does not have federalism implications and does not impose substantial, direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

VI. Congressional Review Act

The Administrator of OIRA has determined that this Treasury decision is a major rule for purposes of the Congressional Review Act (5 U.S.C. 801 *et seq.*) (CRA). Under section 801(3) of the CRA, a major rule takes effect 60 days after the rule is published in the **Federal Register**.

Notwithstanding this requirement, section 808(2) of the CRA allows agencies to dispense with the requirements of section 801 when the agency for good cause finds that such procedure would be impracticable, unnecessary, or contrary to the public interest and the rule shall take effect at such time as the agency promulgating the rule determines. Pursuant to section 808(2) of the CRA, the Treasury Department and the IRS find, for good cause, that a 60-day delay in the effective date is unnecessary and contrary to the public interest.

Following the amendments to section 1031 by the TCJA, the Treasury Department and the IRS published the proposed regulations to provide certainty to taxpayers. In particular, and as emphasized by the wide variety of public comments received in response to the proposed regulations, taxpayers lacked certainty regarding the longstanding role of State and local law in real property determinations for purposes of qualification under section 1031. Consistent with Executive Order 13924 (May 19, 2020), the Treasury Department and the IRS have determined that an expedited effective date of the final regulations would ''give businesses, especially small businesses, the confidence they need to re-open by providing guidance on what the law requires.'' 85 FR 31353–4. Accordingly, the Treasury Department and the IRS have determined that the rules in this Treasury decision shall take effect on the date of publication in the **Federal Register**.

Drafting Information

The principal authors of these regulations are Edward C. Schwartz and Suzanne R. Sinno of the Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

■ **Par. 2.** Section 1.168(i)–1 is amended by:

■ 1. In the last sentence in paragraph (e)(2)(viii)(A), removing ''does not apply.'' at the end of the sentence and adding ''and the distinct asset determination under § 1.1031(a)–3(a)(4) do not apply.'' in its place;

■ 2. In the first sentence in paragraph (m)(1), removing the word ''This'' at the beginning of the sentence and adding ''Except as provided in paragraph (m)(5) of this section, this'' in its place; and

■ 3. Redesignating paragraph (m)(5) as paragraph (m)(6) and adding new paragraph (m)(5).

The addition reads as follows:

§ 1.168(i)–1 General asset accounts.

* * * * *

(m) * * *

(5) *Application of paragraph (e)(2)(viii)(A).* The language ''and the distinct asset determination under § 1.1031(a)–3(a)(4) do not apply.'' in the last sentence of paragraph (e)(2)(viii)(A) of this section applies on or after December 2, 2020. Paragraph (e)(2)(viii)(A) of this section as contained in 26 CFR part 1 edition revised as of April 1, 2020, applies before December 2, 2020.

■ **Par. 3.** Section 1.168(i)–8 is amended by:

■ 1. In the last sentence in paragraph (c)(4)(i), removing ''does not apply'' at the end of the sentence and adding ''and the distinct asset determination under § 1.1031(a)–3(a)(4) do not apply'' in its place;

■ 2. At the beginning of paragraph (j)(1), removing the word ''This'' and adding ''Except as provided in paragraph (j)(5) of this section, this'' in its place;

■ 3. Redesignating paragraph (j)(5) as paragraph (j)(6) and adding new paragraph (j)(5).

The addition reads as follows:

§ 1.168(i)–8 Dispositions of MACRS property.

* * * * *

(j) * * *

(5) *Application of paragraph (c)(4)(i).* The language ''and the distinct asset determination under § 1.1031(a)–3(a)(4) do not apply.'' in the last sentence of paragraph (c)(4)(i) of this section applies on or after December 2, 2020. Paragraph (c)(4)(i) of this section as contained in 26 CFR part 1 edition revised as of April 1, 2020, applies before December 2, 2020.

■ **Par. 4.** Section 1.1031–0 is amended by revising the entry for § 1.1031(a)–1(e) and adding entries for § 1.1031(a)–3 to read as follows:

§ 1.1031–0 Table of contents.

* * * * *

§ 1.1031(a)–1 Property held for productive use in a trade or business or for investment.

* * * * *

(e) Applicability dates.

* * * * *

§ 1.1031(a)–3 Definition of real property.

(a) Real property.

(b) Examples.

(c) Applicability date.

* * * * *

■ **Par. 5.** Section 1.1031(a)–1 is amended by adding paragraph (a)(3) and revising paragraph (e) to read as follows:

§ 1.1031(a)–1 Property held for productive use in trade or business or for investment.

(a) * * *

(3) *Exchanges after 2017.* Pursuant to section 13303 of Public Law 115–97 (131 Stat. 2054), for exchanges beginning after December 31, 2017, section 1031 and §§ 1.1031(a)–1, 1.1031(b)–2, 1.1031(d)–1T, 1.1031(d)–2, 1.1031(j)–1, 1.1031(k)–1, and references to section 1031 in §§ 1.1031(b)–1, 1.1031(c)–1, and 1.1031(d)–1, apply only to qualifying exchanges of real property (within the meaning of § 1.1031(a)–3) that is held for productive use in a trade or business, or for investment, and that is not held primarily for sale.

* * * * *

(e) *Applicability dates*—(1) *Exchanges of partnership interests.* The provisions of paragraph (a)(1) of this section relating to exchanges of partnership interests apply to transfers of property made by taxpayers on or after April 25, 1991.

(2) *Exchanges after 2017.* The provisions of paragraph (a)(3) of this section apply to exchanges beginning after December 2, 2020.

■ **Par. 6.** Section 1.1031(a)–3 is added to read as follows:

§ 1.1031(a)–3 Definition of real property.

(a) *Real property*—(1) *In general.* The term *real property* under section 1031 and §§ 1.1031(a)–1 through 1.1031(k)–1

means land and improvements to land, unsevered natural products of land, and water and air space superjacent to land. Under paragraph (a)(5) of this section, an intangible interest in real property of a type described in this paragraph (a)(1) is real property for purposes of section 1031 and this section. Property that is real property under State or local law as provided in paragraph (a)(6) of this section is real property for purposes of section 1031 and this section.

(2) *Improvements to land*—(i) *In general.* The term *improvements to land* means inherently permanent structures and the structural components of inherently permanent structures.

(ii) *Inherently permanent structures*—(A) *In general.* The term *inherently permanent structure* means any building or other structure that is a distinct asset within the meaning of paragraph (a)(4) of this section and is permanently affixed to real property and that will ordinarily remain affixed for an indefinite period of time. Affixation is considered permanent if it is reasonably expected to last indefinitely based on all the facts and circumstances.

(B) *Building.* A building is any structure or edifice enclosing a space within its walls, and covered by a roof, the purpose of which is, for example, to provide shelter or housing, or to provide working, office, parking, display, or sales space. Buildings include the following distinct assets if permanently affixed: Houses, apartments, hotels, motels, enclosed stadiums and arenas, enclosed shopping malls, factories and office buildings, warehouses, barns, enclosed garages, enclosed transportation stations and terminals, and stores.

(C) *Other inherently permanent structures.* Inherently permanent structures under paragraph (a)(2)(ii) of this section include the following distinct assets, if permanently affixed: In-ground swimming pools; roads; bridges; tunnels; paved parking areas, parking facilities, and other pavements; special foundations; stationary wharves and docks; fences; inherently permanent advertising displays for which an election under section 1033(g)(3) is in effect; inherently permanent outdoor lighting facilities; railroad tracks and signals; telephone poles; power generation and transmission facilities; permanently installed telecommunications cables; microwave transmission, cell, broadcasting, and electric transmission towers; oil and gas pipelines; offshore platforms, derricks, oil and gas storage tanks; and grain storage bins and silos. Affixation to real property may be accomplished by weight alone. If property is not listed as an inherently permanent structure in paragraph (a)(2)(ii)(B) or (C) of this section, the determination of whether the property is an inherently permanent structure under paragraph (a)(2)(ii) of this section is based on the following factors—

(*1*) The manner in which the distinct asset is affixed to real property;

(*2*) Whether the distinct asset is designed to be removed or to remain in place;

(*3*) The damage that removal of the distinct asset would cause to the item itself or to the real property to which it is affixed;

(*4*) Any circumstances that suggest the expected period of affixation is not indefinite; and

(*5*) The time and expense required to move the distinct asset.

(iii) *Structural components*—(A) *In general.* The term *structural component* means any distinct asset, within the meaning of paragraph (a)(4) of this section, that is a constituent part of, and integrated into, an inherently permanent structure. If interconnected assets work together to serve an inherently permanent structure (for example, systems that provide a building with electricity, heat, or water), the assets are analyzed together as one distinct asset that may be a structural component. A structural component may qualify as real property only if the taxpayer holds its interest in the structural component together with a real property interest in the space in the inherently permanent structure served by the structural component. If a distinct asset is customized, the customization does not affect whether the distinct asset is a structural component. Tenant improvements to a building that are inherently permanent or otherwise classified as real property within the meaning of this paragraph (a)(2)(iii) are real property under this section. However, property produced for sale, such as bricks, nails, paint, and windowpanes, that is not real property in the hands of the producing taxpayer or a related person, as defined in section 1031(f)(3), but that may be incorporated into real property by an unrelated buyer, is not treated as real property by the producing taxpayer.

(B) *Examples of structural components.* Structural components include the following items, provided the item is a constituent part of, and integrated into, an inherently permanent structure: Walls; partitions; doors; wiring; plumbing systems; central air conditioning and heating systems; pipes and ducts; elevators and escalators; floors; ceilings; permanent coverings of walls, floors, and ceilings; insulation; chimneys; fire suppression systems, including sprinkler systems and fire alarms; fire escapes; security systems; humidity control systems; and other similar property. If a component of a building or inherently permanent structure is a distinct asset and is not listed as a structural component in this paragraph (a)(2)(iii)(B), the determination of whether the component is a structural component under this paragraph (a)(2)(iii) is based on the following factors—

(*1*) The manner, time, and expense of installing and removing the component;

(*2*) Whether the component is designed to be moved;

(*3*) The damage that removal of the component would cause to the item itself or to the inherently permanent structure to which it is affixed; and

(*4*) Whether the component is installed during construction of the inherently permanent structure.

(3) *Unsevered natural products of land.* Unsevered natural products of land, including growing crops, plants, and timber; mines; wells; and other natural deposits, generally are treated as real property for purposes of this section. Natural products and deposits, such as crops, timber, water, ores, and minerals, cease to be real property when they are severed, extracted, or removed from the land.

(4) *Distinct asset*—(i) *In general.* For this section, a distinct asset is analyzed separately from any other assets to which the asset relates to determine if the asset is real property, whether as land, an inherently permanent structure, or a structural component of an inherently permanent structure. Buildings and other inherently permanent structures are distinct assets. Assets and systems listed as a structural component in paragraph (a)(2)(iii)(B) of this section are treated as distinct assets.

(ii) *Facts and circumstances.* The determination of whether a particular separately identifiable item of property is a distinct asset is based on all the facts and circumstances. In particular, the following factors must be taken into account—

(A) Whether the item is customarily sold or acquired as a single unit rather than as a component part of a larger asset;

(B) Whether the item can be separated from a larger asset, and if so, the cost of separating the item from the larger asset;

(C) Whether the item is commonly viewed as serving a useful function independent of a larger asset of which it is a part; and

(D) Whether separating the item from a larger asset of which it is a part

impairs the functionality of the larger asset.

(5) *Intangible assets*—(i) *In general.* Intangible assets that are real property for purposes of section 1031 and this section include the following items: Fee ownership; co-ownership; a leasehold; an option to acquire real property; an easement; stock in a cooperative housing corporation; shares in a mutual ditch, reservoir, or irrigation company described in section 501(c)(12)(A) of the Code if, at the time of the exchange, such shares have been recognized by the highest court of the State in which the company was organized, or by a State statute, as constituting or representing real property or an interest in real property; and land development rights. Similar interests are real property for purposes of section 1031 and this section if the intangible asset derives its value from real property or an interest in real property and is inseparable from that real property or interest in real property. The following intangible assets are not real property for purposes of section 1031 and this section, regardless of the classification of such property under State or local law—

(A) Stock not described in paragraph (a)(5)(i) of this section, bonds, or notes;

(B) Other securities or evidences of indebtedness or interest;

(C) Interests in a partnership (other than an interest in a partnership that has in effect a valid election under section 761(a) to be excluded from the application of all of subchapter K);

(D) Certificates of trust or beneficial interests; and

(E) Choses in action.

(ii) *Licenses and permits.* A license, permit, or other similar right that is solely for the use, enjoyment, or occupation of land or an inherently permanent structure and that is in the nature of a leasehold, easement, or other similar right, generally is an interest in real property under this section. However, a license or permit to engage in or operate a business on real property is not real property or an interest in real property, regardless of its classification under State or local law.

(6) *State or local law.* Except as otherwise provided in paragraph (a)(5) of this section, property is real property within the meaning of paragraph (a)(1) of this section under State or local law if, on the date it is transferred in an exchange, the property is real property under the law of the State or local jurisdiction in which that property is located.

(7) *No inference outside of section 1031.* The rules provided in this section concerning the definition of real property apply only for purposes of section 1031. No inference is intended with respect to the classification or characterization of property for other purposes of the Code, such as depreciation and sections 1245 and 1250. For example, a structure or a portion of a structure may be section 1245 property for depreciation purposes and for determining gain under section 1245, notwithstanding that the structure or the portion of the structure is real property under this section. Also, a taxpayer transferring relinquished property that is section 1245 property in a section 1031 exchange is subject to the gain recognition rules under section 1245 and the regulations under section 1245, notwithstanding that the relinquished property or replacement property is real property under this section. In addition, the taxpayer must follow the rules of section 1245 and the regulations under section 1245, and section 1250 and the regulations under section 1250, based on the determination of the relinquished property and replacement property being, in whole or in part, section 1245 property or section 1250 property under those Code sections and not under this section.

(b) *Examples.* The following examples illustrate the provisions of this section. In each example, unless otherwise provided, the State or local law of the applicable jurisdiction in which the property at issue is located does not address whether the property is real property.

(1) *Example 1: Natural products of land.* A owns land with perennial fruit-bearing plants that A harvests annually. The unsevered plants are natural products of the land within the meaning of paragraph (a)(3) of this section and thus are real property for purposes of section 1031. A annually harvests fruit from the plants. Upon severance from the land, the harvested fruit ceases to be part of the land and therefore is not real property. Storage of the harvested fruit upon or within real property does not cause the harvested fruit to be real property.

(2) *Example 2: Water space superjacent to land.* B owns a marina comprised of U-shaped boat slips and end ties. The U-shaped boat slips are spaces on the water that are surrounded by a dock on three sides. The end ties are spaces on the water at the end of a slip or on a long, straight dock. B rents the boat slips and end ties to boat owners. The boat slips and end ties are water space superjacent to land and thus are real property within the meaning of paragraph (a)(1) of this section.

(3) *Example 3: Indoor sculpture.* (i) C owns an office building and a large sculpture in the atrium of the building. The sculpture measures 30 feet tall by 18 feet wide and weighs five tons. The building was specifically designed to support the sculpture, which is permanently affixed to the building by supports embedded in the building's foundation. The sculpture was constructed within the building. Removal would be costly and time consuming and would destroy the sculpture. The sculpture is reasonably expected to remain in the building indefinitely.

(ii) The sculpture is not an inherently permanent structure listed in paragraph (a)(2)(ii)(C) of this section, and, therefore, C must use the factors provided in paragraphs (a)(2)(ii)(C)(*1*) through (*5*) of this section to determine whether the sculpture is an inherently permanent structure. The sculpture—

(A) Is permanently affixed to the building by supports embedded in the building's foundation;

(B) Is not designed to be removed and is designed to remain in place indefinitely;

(C) Would be damaged if removed and would damage the building to which it is affixed;

(D) Is expected to remain in the building indefinitely; and

(E) Would require significant time and expense to move.

(iii) The factors described in paragraphs (a)(2)(ii)(C)(*1*) through (*5*) of this section all support the conclusion that the sculpture is an inherently permanent structure within the meaning of paragraph (a)(2)(ii)(A) of this section. Therefore, the sculpture is real property.

(4) *Example 4: Bus shelters.* (i) D owns 400 bus shelters, each of which consists of four posts, a roof, and panels enclosing two or three sides. D enters into a long-term lease with a local transit authority for use of the bus shelters. Each bus shelter is prefabricated from steel and is bolted to the sidewalk. Bus shelters are disassembled and moved when bus routes change. Moving a bus shelter takes less than a day and does not significantly damage either the bus shelter or the real property to which it was affixed.

(ii) The bus shelters are not permanently affixed enclosed transportation stations or terminals, are not buildings under paragraph (a)(2)(ii)(B) of this section, nor are they listed as types of other inherently permanent structures in paragraph (a)(2)(ii)(C) of this section. Therefore, the bus shelters must be analyzed to determine whether they are inherently

permanent structures using the factors provided in paragraphs (a)(2)(ii)(C)(*1*) through (*5*) of this section. The bus shelters—

(A) Are not permanently affixed to the land or an inherently permanent structure;

(B) Are designed to be removed and not remain in place indefinitely;

(C) Would not be damaged if removed and would not damage the sidewalks to which they are affixed;

(D) Will not remain affixed indefinitely; and

(E) Would not require significant time and expense to move.

(iii) The factors described in paragraphs (a)(2)(ii)(C)(*1*) through (*5*) of this section all support the conclusion that the bus shelters are not inherently permanent structures within the meaning of paragraph (a)(2)(ii) of this section. Thus, the bus shelters are not inherently permanent structures within the meaning of paragraph (a)(2)(ii) of this section and, therefore, are not real property.

(5) *Example 5: Industrial 3D printer and generator.* (i) E owns a building that it uses in its trade or business of manufacturing airplane parts. The building includes an industrial 3D printer that can print airplane wings and an electrical generator that serves the building and the 3D printer in a backup capacity. The 3D printer weighs 12 tons, is designed to remain in place indefinitely once installed in the building, and its removal would be time-consuming and very costly, and would cause significant damage to the building. The 3D printer was installed during the building's construction. The generator also was installed during construction and is designed to remain in place indefinitely once installed. Although costly and time-consuming to remove, removal of the generator will not result in substantial damage to the generator or the building.

(ii) The 3D printer is not listed as an example of a structural component under paragraph (a)(2)(iii)(B) of this section. Therefore, the 3D printer must be analyzed to determine whether it is a structural component using the factors provided in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section. The 3D printer—

(A) Is time-consuming and costly to move;

(B) Is not designed to be moved;

(C) If removed, would cause significant damage to the building in which it is located; and

(D) Was installed during construction of the building.

(iii) The factors described in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section support the conclusion that the 3D printer is a structural component of E's building and real property under this section. Thus, the 3D printer is real property.

(iv) The electrical generator also is not listed as an example of a structural component under paragraph (a)(2)(iii)(B) of this section and must be analyzed to determine whether it is a structural component using the factors provided in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section. The generator—

(A) Is time-consuming and costly to move;

(B) Is not designed to be moved;

(C) If removed, would not result in significant damage to the generator or the building in which it is located; and

(D) Was installed during construction of the building.

(v) The factors described in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section, considered in the aggregate, support the conclusion that the generator is a structural component of E's building. Although the generator's removal would not result in significant damage to the generator or to E's building, that factor does not outweigh the factors supporting the conclusion that it is a structural component. Consequently, the generator is a structural component of E's building and real property under this section.

(6) *Example 6: Raised flooring for industrial 3D printer.* (i) The facts are the same as in paragraph (b)(5), *Example 5,* except that E, when installing its 3D printer, also installed a raised flooring system for the purpose of facilitating the operation of the 3D printer. The raised flooring system is not designed or constructed to remain permanently in place. Rather, the raised flooring system can be removed, without any substantial damage to the system itself or to the building, and then reused. The raised flooring was installed during the building's construction.

(ii) Although floors are listed as an example of a structural component under paragraph (a)(2)(iii)(B) of this section, the raised flooring system installed to facilitate the operation of E's 3D printer is not a constituent part of, and integrated into, an inherently permanent structure as required by paragraph (a)(2)(iii)(A) of this section and, therefore, is not flooring as listed in paragraph (a)(2)(iii)(B) of this section. Thus, the raised flooring must be analyzed to determine whether it is a structural component of E's building (within the meaning of paragraph (a)(2)(iii) of this section) using the factors provided in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section. The raised flooring—

(A) Is installed and removed quickly and with little expense;

(B) Is designed to be moved and is not designed specifically for the particular building of which it is a part;

(C) Is not damaged, and the building is not damaged, upon its removal; and

(D) Was installed during construction of the building.

(iii) The factors described in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section, considered in the aggregate, support the conclusion that the raised flooring is not a structural component of E's building within the meaning of paragraph (a)(2)(iii) of this section. Although the raised flooring was installed during construction of the building, that factor does not outweigh the factors supporting the conclusion that the flooring is not a structural component. Therefore, the raised flooring is not real property.

(7) *Example 7: Steam turbine.* (i) F owns a building with a large steam turbine attached as a fixture to the building. The steam turbine is a component of a system used for the commercial production of electricity for sale to customers in the ordinary course of F's business as an electric utility. The steam turbine also generates electricity for F's building. The steam turbine takes up a substantial portion of the building and is designed to remain in place indefinitely once installed in F's building. The steam turbine was installed during the construction of the building and its removal would be costly and cause damage to the building.

(ii) The steam turbine is not listed as an example of a structural component under paragraph (a)(2)(iii)(B) of this section and must be analyzed to determine whether it is a structural component using the factors provided in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section. The steam turbine—

(A) Is costly to remove from the building in which it is located;

(B) Is not designed to be moved;

(C) If removed, would cause damage to the building; and

(D) Was installed during construction of the building.

(iii) The factors described in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section support the conclusion that the steam turbine is a structural component of F's building and real property under this section. Thus, the steam turbine is real property.

(8) *Example 8: Partitions.* (i) G owns an office building that it leases to tenants. The building includes partitions owned by G that are used to delineate space within the building. The

office building has two types of interior, non-load-bearing drywall partition systems: A conventional drywall partition system (Conventional Partition System) and a modular drywall partition system (Modular Partition System). Neither the Conventional Partition System nor the Modular Partition System was installed during construction of the office building. Conventional Partition Systems are comprised of fully integrated gypsum board partitions, studs, joint tape, and covering joint compound. Modular Partition Systems are comprised of assembled panels, studs, tracks, and exposed joints. Both the Conventional Partition System and the Modular Partition System reach from the floor to the ceiling. In addition, both are distinct assets as described in paragraph (a)(4) of this section.

(ii) Depending on the needs of a new tenant, the Conventional Partition System may remain in place when a tenant vacates the premises. The Conventional Partition System is integrated into the office building and is designed and constructed to remain in areas not subject to reconfiguration or expansion. The Conventional Partition System can be removed only by demolition, and, once removed, neither the Conventional Partition System nor its components can be reused. Removal of the Conventional Partition System causes substantial damage to the Conventional Partition System itself, but does not cause substantial damage to the building.

(iii) Modular Partition Systems are typically removed when a tenant vacates the premises. Modular Partition Systems are not designed or constructed to remain permanently in place. Modular Partition Systems are designed and constructed to be movable. Each Modular Partition System can be readily removed, remains in substantially the same condition as before, and can be reused. Removal of a Modular Partition System does not cause any substantial damage to the Modular Partition System itself or to the building. The Modular Partition System may be moved to accommodate the reconfigurations of the interior space within the office building for various tenants that occupy the building.

(iv) The Conventional Partition System is comprised of walls that are integrated into an inherently permanent structure and are listed as structural components in paragraph (a)(2)(iii)(B) of this section. Thus, the Conventional Partition System is real property.

(v) The Modular Partition System is not integrated into the building as required by paragraph (a)(2)(iii)(A) of this section and, therefore, is not listed in paragraph (a)(2)(iii)(B) of this section. Thus, the Modular Partition System must be analyzed to determine whether it is a structural component using the factors provided in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section. The Modular Partition System—

(A) Is installed and removed quickly and with little expense;

(B) Is designed to be moved and is not designed specifically for the particular building of which it is a part;

(C) Is not damaged, and the building is not damaged, upon its removal; and

(D) Was not installed during construction of the building.

(vi) The factors described in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section support the conclusion that the Modular Partition System is not a structural component of G's office building within the meaning of paragraph (a)(2)(iii) of this section. Therefore, the Modular Partition System is not real property.

(9) *Example 9: Pipeline transmission system.* (i) H owns a natural gas pipeline transmission system that provides a conduit to transport natural gas from unrelated third-party producers and gathering facilities to unrelated third-party distributors and end users. The pipeline transmission system is comprised of underground pipelines, isolation valves and vents, pressure control and relief valves, meters, and compressors. Each of these distinct assets was installed during construction of the pipeline transmission system and each was designed to remain permanently in place.

(ii) The pipelines are permanently affixed and are listed as other inherently permanent structures in paragraph (a)(2)(ii)(C) of this section. Thus, the pipelines are real property.

(iii) Isolation valves and vents are placed at regular intervals along the pipelines to isolate and evacuate sections of the pipelines in case there is need for a shut-down or maintenance of the pipelines. Pressure control and relief valves are installed at regular intervals along the pipelines to provide overpressure protection. The isolation valves and vents and pressure control and relief valves are not listed in paragraph (a)(2)(iii)(B) of this section and, therefore, must be analyzed to determine whether they are structural components using the factors provided in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section. The isolation valves and vents and pressure control and relief valves—

(A) Are time consuming and expensive to install and remove from the pipelines;

(B) Are designed specifically for the particular pipelines for which they are a part;

(C) Will sustain damage and will damage the pipelines if removed; and

(D) Were installed during construction of the pipelines.

(iv) The factors in paragraphs (a)(2)(iii)(B)(*1*) through (*4*) of this section support the conclusion that the isolation valves and vents and pressure control and relief valves are structural components of H's pipelines within the meaning of paragraph (a)(2)(iii) of this section. Therefore, the isolation valves and vents and pressure control and relief valves are real property.

(v) Meters are used to measure the natural gas passing into or out of the pipeline transmission system for purposes of determining the end users' consumption. Over long distances, pressure is lost due to friction in the pipeline transmission system. Compressors are required to add pressure to transport natural gas through the entirety of the pipeline transmission system. H installed meters and compressors during the construction of the pipelines. However, unlike other types of such meters and compressors, these particular meters and compressors are not time consuming and expensive to install and remove from the pipelines; are not designed specifically for the particular pipelines for which they are a part; and their removal does not cause damage to the asset or the pipelines if removed. Therefore, the meters and compressors installed by H are not structural components within the meaning of paragraph (a)(2)(iii) of this section and, therefore, are not real property.

(10) *Example 10: State or local law determination of property.* (i) J owns water pipeline in State X that it wants to exchange for cell phone towers located in State Y. On the date that J transfers the water pipeline in an exchange for the cell phone towers, the water pipeline is classified as real property under the law of State X, the jurisdiction in which the water pipeline is located.

(ii) The water pipeline is real property under paragraphs (a)(1) and (a)(6) of this section, regardless of whether the water pipeline is listed as an inherently permanent structure or a structural component of an inherently permanent structure, or is real property under the factors listed in paragraph (a)(2)(ii)(C) or (a)(2)(iii)(B) of this section.

(iii) Cell phone towers are listed as an inherently permanent structure under

paragraph (a)(2)(ii)(C) of this section. Thus, the cell phone towers that J acquires in the exchange for the water pipeline are real property under this section, regardless of the State or local characterization of the cell phone towers or whether the cell phone towers are real property under the factors in paragraph (a)(2)(ii)(C) or (a)(2)(iii)(B) of this section.

(11) *Example 11: Land use permit.* K receives a special use permit from the government to place a cell tower on Federal Government land that abuts a Federal highway. Government regulations provide that the permit is not a lease of the land, but is a permit to use the land for a cell tower. Under the permit, the government reserves the right to cancel the permit and compensate K if the site is needed for a higher public purpose. The permit is in the nature of a leasehold that allows K to place a cell tower in a specific location on government land. Therefore, the permit is an interest in real property under paragraph (a)(5) of this section.

(12) *Example 12: License to operate a business.* L owns a building and receives a license from State A to operate a casino in the building. The license applies only to K's building and cannot be transferred to another location. L's building is an inherently permanent structure under paragraph (a)(2)(ii)(A) of this section and, therefore, is real property. However, L's license to operate a casino is not a right for the use, enjoyment, or occupation of L's building, but is rather a license to engage in or operate the casino business in the building. Therefore, the casino license is not real property or an interest in real property under paragraph (a)(5)(ii) of this section.

(c) *Applicability date.* This section applies to exchanges beginning after December 2, 2020.

■ **Par. 7.** Section 1.1031(k)–1 is amended by:

■ 1. In paragraph (d)(2), removing ''$87,500'' and adding in its place ''$62,500'' each place it appears;

■ 2. Removing '', and'' at the end of paragraph (g)(7)(i) and adding a semicolon in its place;

■ 3. Removing the period at the end of paragraph (g)(7)(ii) and adding ''; and'' in its place;

■ 4. Adding paragraph (g)(7)(iii);

■ 5. In paragraph (g)(8), designating *Examples 1* through *5* as paragraphs (g)(8)(i) through (v), respectively;

■ 6. In newly designated paragraph (g)(8)(i):

■ a. Redesignating paragraph (g)(8)(i)(i) as paragraph (g)(8)(i)(A);

■ b. In newly designated paragraph (g)(8)(i)(A), redesignating paragraphs (g)(8)(i)(A)(A) and (B) as paragraphs (g)(8)(i)(A)(*1*) and (*2*), respectively;

■ c. Designating the undesignated paragraph immediately following newly redesignated paragraph (g)(8)(i)(A)(*2*) as paragraph (g)(8)(i)(A)(*3*); and

■ d. In newly designated paragraph (g)(8)(i) redesignating paragraph (g)(8)(i)(ii) as paragraph (g)(8)(i)(B);

■ 7. In newly designated paragraph (g)(8)(ii):

■ a. Redesignate old paragraph (i) as paragraph (A);

■ b. Redesignate old paragraph (A) as paragraph (*1*);

■ c. Redesignate old paragraphs (*1*) and (*2*) as paragraphs (*i*) and (*ii*), respectively;

■ d. Redesignate old paragraphs (B) and (C) as paragraphs (*2*) and (*3*), respectively;

■ e. Designating the undesignated paragraph immediately following newly redesignated paragraph (g)(8)(ii)(A)(*3*) as paragraph (g)(8)(ii)(A)(*4*); and

■ f. Redesignate old paragraphs (ii) and (iii) as paragraphs (B) and (C), respectively;

■ 8. In newly designated paragraph (g)(8)(iii), redesignating old paragraphs (i) through (v) as paragraphs (A) through (E), respectively;

■ 9. In newly designated paragraph (g)(8)(iv), redesignating old paragraphs (i) through (iii) as paragraphs (A) through (C), respectively;

■ 10. In newly designated paragraph (g)(8)(v), redesignating old paragraphs (i) through (iii) as paragraphs (A) through (C), respectively;

■ 11. Adding paragraph (g)(8)(vi); and

■ 12. Adding paragraph (g)(9).

The additions read as follows:

§ 1.1031(k)–1 Treatment of deferred exchanges.

* * * * *

(g) * * *

(7) * * *

(iii) Personal property generally resulting in gain recognition under section 1031(b) that is incidental to real property acquired in an exchange. For purposes of this paragraph (g)(7), personal property is incidental to real property acquired in an exchange if—

(A) In standard commercial transactions, the personal property is typically transferred together with the real property; and

(B) The aggregate fair market value of the property described in paragraph (g)(7)(iii)(A) of this section transferred with the real property does not exceed 15 percent of the aggregate fair market value of the replacement real property or properties received in the exchange.

* * * * *

(8) * * *

(vi) *Example 6.* (A) In 2020, B transfers to C real property with a fair market value of $1,100,000 and an adjusted basis of $400,000. B's replacement property is an office building and, as a part of the exchange, B also will acquire certain office furniture in the building that is not real property, which is industry practice in a transaction of this type. The fair market value of the real property B will acquire is $1,000,000 and the fair market value of the personal property is $100,000.

(B) In a standard commercial transaction, the buyer of an office building typically also acquires some or all of the office furniture in the building. The fair market value of the personal property B will acquire does not exceed 15 percent of the fair market value of the office building B will acquire. Accordingly, under paragraph (g)(7)(iii) of this section, the personal property is incidental to the real property in the exchange and is disregarded in determining whether the taxpayer's rights to receive, pledge, borrow or otherwise obtain the benefits of money or non-like-kind property are expressly limited as provided in paragraph (g)(6) of this section. Upon the receipt of the personal property, B recognizes gain of $100,000 under section 1031(b), the lesser of the realized gain on the disposition of the relinquished property, $700,000, and the fair market value of the non-like-kind property B acquired in the exchange, $100,000.

(9) *Applicability date.* Paragraphs (g)(7)(iii) and (g)(8)(vi) of this section apply to exchanges beginning after December 2, 2020.

* * * * *

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: November 18, 2020.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2020–26313 Filed 11–30–20; 4:15 pm]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2018–0815; FRL 10016–14–OAR]

RIN 2060–AU39

Test Methods and Performance Specifications for Air Emission Sources; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) is correcting a final rule that was published in the **Federal Register** on October 7, 2020, and will be effective on December 7, 2020. The final rule corrected and updated regulations for source testing of emissions. This correction does not change any final action taken by the EPA on October 7, 2020; this action merely provides further clarification on the amendatory instructions for Method 311.

DATES: The final rule is effective on December 7, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0815. All documents in the docket are listed at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Lula H. Melton, Office of Air Quality Planning and Standards, Air Quality Assessment Division (E143–02), Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–2910; fax number: (919) 541–0516; email address: *melton.lula@epa.gov.*

SUPPLEMENTARY INFORMATION: In FR doc 2020–18824 at 85 FR 63394 in the issue of October 7, 2020, the following correction to an amendatory instruction to ''Appendix A to Part 63'' is made.

On page 63419, in the second column, amendatory instruction 34.c is corrected to read: ''c. In Method 311, revising sections 1.1 and 17.4 through 17.6;''

Anne Austin,

Principal Deputy Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2020–23690 Filed 12–1–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 320

[EPA–HQ–OLEM–2019–0085, EPA–HQ–OLEM–2019–0086, EPA–HQ–OLEM–2019–0087, FRL–10017–87–OLEM]

RIN 2050–AH03

Financial Responsibility Requirements Under CERCLA Section 108(b) for Facilities in the Electric Power Generation, Transmission, and Distribution Industry; the Petroleum and Coal Products Manufacturing Industry; and the Chemical Manufacturing Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final actions.

SUMMARY: EPA (or the Agency) is finalizing its proposed decisions to not impose financial responsibility requirements under section 108(b) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) for facilities in three industry sectors: The electric power generation, transmission, and distribution industry, pursuant to EPA's proposal of July 29, 2019; the petroleum and coal products manufacturing industry, pursuant to EPA's proposal of December 23, 2019; and the chemical manufacturing industry, pursuant to EPA's proposal of February 21, 2020. Today's final rulemakings are based on the individual administrative records for each of the three proposed rulemakings, supported by additional analysis conducted in consideration of comments received in the public comment period for each proposed rule. In particular, after examining the existing environmental protections and regulations in place today and analyzing the Superfund program's experience cleaning up sites in each industry, the Agency concluded that facilities in these three industries operating under a modern regulatory framework do not present a level of risk that warrants financial responsibility requirements under CERCLA section 108(b). Today's final rulemakings are based on the record for these rulemakings, and do not affect EPA's authority to take a response or enforcement action under CERCLA with respect to any particular facility or industry, and do not affect the Agency's authorities that may apply to particular facilities under other environmental statutes. This combined final rulemaking comprises the Agency's final actions on each of the three proposed rules.

DATES: These final actions are effective on January 4, 2021.

ADDRESSES: EPA has established a docket for these actions under Docket ID No. EPA–HQ–OLEM–2019–0085, EPA–HQ–OLEM–2019–0086, and EPA–HQ–OLEM–2019–0087. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For more information on this document, contact Charlotte Mooney, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, Mail Code 5303P, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone (703) 308–7025 or (email) *mooney.charlotte@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
A. Overview
B. Purpose of This Action
II. Authority
III. Background Information
A. Overview of Section 108(b) and Other CERCLA Provisions
B. History of Section 108(b) Rulemakings
1. 2009 Identification of Priority Classes of Facilities for Development of CERCLA section 108(b) Financial Responsibility Requirements
2. Additional Classes 2010 Advance Notice of Proposed Rulemaking
3. 2014 Petition for Writ of Mandamus
4. Additional Classes 2017 Notice of Intent To Proceed With Rulemakings
5. The Hardrock Mining Proposal and Final Rulemaking
a. Proposed Rule
b. Decision to Not Impose Requirements
c. Litigation and D.C. Circuit Decision
IV. Statutory Interpretation
V. Electric Power Generation, Transmission and Distribution Industry
A. Proposed Rule
B. Summary of Key Comments Received and Agency Response
1. Comments in Support of the Proposal
2. Comments Opposed to the Proposal

C. Decision to Not Impose Requirements
VI. Petroleum and Coal Products Manufacturing Industry
A. Proposed Rule
B. Summary of Key Comments Received and Agency Response
1. Comments in Support of the Proposal
2. Comments Opposed to the Proposal
C. Decision to Not Impose Requirements
VII. Chemical Manufacturing Industry
A. Proposed Rule
B. Summary of Key Comments Received and Agency Response
1. Comments in Support of the Proposal
2. Comments Opposed to the Proposal
C. Decision to Not Impose Requirements
VIII. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs
C. Paperwork Reduction Act (PRA)
D. Regulatory Flexibility Act (RFA)
E. Unfunded Mandates Reform Act (UMRA)
F. Executive Order 13132: Federalism
G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
J. National Technology Transfer and Advancement Act
K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
L. Congressional Review Act

I. Executive Summary

A. Overview

Section 108(b) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) directs EPA to develop regulations that require classes of facilities to establish and maintain evidence of financial responsibility consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances. The statute further requires that the level of financial responsibility be established to protect against the level of risk that the President, in his/her discretion, believes is appropriate, based on factors including the payment experience of the Hazardous Substance Superfund (Fund). The President's authority under this section for non-transportation-related facilities has been delegated to the EPA Administrator.

On January 6, 2010, EPA published an Advance Notice of Proposed Rulemaking (ANPRM),[1] in which the Agency identified three industrial sectors, to follow the hardrock mining industry, for the development, as necessary, of proposed section 108(b) regulations. Those industries identified were the electric power generation, transmission, and distribution; petroleum and coal products manufacturing; and chemical manufacturing industries. In August 2014, the Idaho Conservation League, Earthworks, Sierra Club, Amigos Bravos, Great Basin Resource Watch, and Communities for a Better Environment filed a lawsuit in the U.S. Court of Appeals for the District of Columbia Circuit, seeking a writ of mandamus requiring issuance of CERCLA section 108(b) financial responsibility rules for the hardrock mining industry, and for the three additional industries identified in the 2010 ANPRM. Following oral arguments, EPA and the petitioners submitted a joint motion for an order on consent, filed on August 31, 2015, which included a schedule for further administrative proceedings under CERCLA section 108(b). The court order granting the motion was issued on January 29, 2016.

In addition to requiring EPA to publish a proposed rule on hardrock mining financial responsibility requirements by December 1, 2016, the January 2016 order required EPA to sign for publication in the **Federal Register** a determination whether EPA will issue a notice of proposed rulemaking on financial responsibility requirements under section 108(b) in the electric power generation, transmission, and distribution industry; the petroleum and coal products manufacturing industry; and the chemical manufacturing industry by December 1, 2016. EPA signed the required determination on December 1, 2016; the document was published on January 11, 2017[2] and announced EPA's intent to proceed with rulemakings for all three of the additional classes.

B. Purpose of This Action

The purpose of today's action, containing three final rulemakings, is to finalize the Agency's proposed rulemaking decisions that financial responsibility requirements under CERCLA section 108(b) are not warranted for facilities in the electric power generation, transmission, and distribution industry; the petroleum and coal products manufacturing industry; and the chemical manufacturing industry. EPA has reached these conclusions based on the analyses described in the proposed rules for (1) the electric power generation, transmission, and distribution industry proposal (84 FR 36535), (2) the petroleum and coal products manufacturing industry proposal (84 FR 74067), and (3) the chemical manufacturing industry proposal (85 FR 10128); consideration of comments on those proposed rules; and additional analyses based on those comments. The evidence examined in each of these analyses has led EPA to the finding that the degree and duration of risk posed by each of these three industries does not warrant financial responsibility requirements under CERCLA section 108(b).

EPA is publishing this document, containing three final rulemakings, to comply with its obligations under CERCLA section 108(b) to determine whether requirements that classes of facilities establish and maintain evidence of financial responsibility are appropriate, and to satisfy the Agency's obligations under the Mandamus Order issued on January 29, 2016. *See In re: Idaho Conservation League, et al.,* No. 14–1149. A copy of the Mandamus Order can be found in the docket for this document.

These final rulemakings are not applicable to and do not affect, limit, or restrict EPA's authority to take a response action or enforcement action under CERCLA at any facility in the electric power generation, transmission, and distribution industry; the petroleum and coal products manufacturing industry; or the chemical manufacturing industry, including any requirements for financial responsibility as part of such response action. The set of facts in the rulemaking record related to the individual facilities discussed in the proposed and final rulemakings support the Agency's decision not to issue financial responsibility requirements under section 108(b) for these industries as a class. At the same time, a different set of facts could demonstrate a need for a CERCLA response action at an individual site. These rulemakings do not affect the Agency's authority under other authorities that may apply to individual facilities, such as the Clean Air Act (CAA), the Clean Water Act (CWA), the Resource Conservation and Recovery Act (RCRA), and the Toxic Substances Control Act (TSCA).

This document is structured to present the Agency's final rulemakings for the electric power generation, transmission, and distribution industry; the petroleum and coal products manufacturing industry; and the chemical manufacturing industry. As

[1] 75 FR 816 (Jan. 6, 2010).
[2] 82 FR 3512 (Jan. 11, 2017).

the three rulemakings contained in this document share common features, such as statutory authority and regulatory history, background information which is consistent across the three industries and intended to be applied to all industries is presented first in a unified manner. Additionally, certain executive orders that relate or may relate to these rules are discussed in unison in the last section of this document. Discussion of public comments received on the proposed rules for each industry and industry specific analyses, which were relied upon to reach unique final rulemaking decisions, is presented separately. The Agency's conclusions for each industry were reached based on the specific consideration of risk for each industry.

II. Authority

EPA is issuing this document, containing three final rulemakings, under the authority of sections 101, 104, 108 and 115 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. sections 9601, 9604, 9608 and 9615, and Executive Order 12580 (52 FR 2923, January 29, 1987).

III. Background Information

A. Overview of Section 108(b) and Other CERCLA Provisions

CERCLA, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), establishes a comprehensive environmental response and cleanup program. Generally, CERCLA authorizes EPA [3] to undertake removal or remedial actions in response to any release or threatened release into the environment of ''hazardous substances'' or, in some circumstances, any other ''pollutant or contaminant.'' As defined in CERCLA section 101, removal actions include actions to ''prevent, minimize, or mitigate damage to the public health or welfare or to the environment,'' and remedial actions are ''actions consistent with [a] permanent remedy[.]'' Remedial and removal actions are jointly referred to as ''response actions.'' CERCLA section 111 authorizes the use of the Hazardous Substance Superfund (Fund) established under title 26, United States Code, to finance response actions undertaken by EPA. In addition, CERCLA section 106 gives EPA [4] authority to compel action by liable parties in response to a release or threatened release of a hazardous substance that may pose an ''imminent and substantial endangerment'' to public health or welfare or the environment.

The authorities established by CERCLA work alongside other EPA statutes which created programs designed to control releases of contaminants, such as the CAA, the CWA, RCRA, and TSCA. Features of the RCRA program, in particular, complement objectives of CERCLA and help to prevent the types of releases that might become CERCLA sites. Pursuant to RCRA, as amended by HSWA (Hazardous and Solid Waste Amendments), statutory and regulatory requirements, RCRA established a system of cradle-to-grave management of hazardous wastes. Implemented by EPA and authorized state RCRA programs, RCRA permitting requirements for hazardous waste treatment, storage, and disposal (TSD) facilities detail technical standards, set reporting requirements, and include a requirement to establish financial assurance. Where releases do occur, the corrective action program established by RCRA provides a mechanism to clean up contamination as well as authority to require financial assurance. Under RCRA's corrective action program, EPA requires owners and operators of TSDs to investigate and clean up releases of hazardous waste and hazardous constituents from any solid waste management units, thus reducing the likelihood that these facilities would require cleanup under Superfund. RCRA's role was considered so relevant that financial assurance requirements established under RCRA Subtitle C (RCRA §§ 3001–3023) were referenced in Senate Report on legislation that was later enacted as CERCLA section 108(b). That language stated ''[I]t is not the intention of the Committee that operators of facilities covered by section 3004(6) of that Act be subject to two financial responsibility requirements for the same dangers.'' [5]

CERCLA section 107 imposes liability for response costs on a variety of parties, including certain past owners and operators, current owners and operators, and certain generators, arrangers, and transporters of hazardous substances. Such parties are liable for certain costs and damages, including all costs of removal or remedial action incurred by the Federal Government, so long as the costs incurred are ''not inconsistent with the national contingency plan'' (the National Oil and Hazardous Substances Pollution Contingency Plan or NCP).[6] Section 107 also imposes liability for natural resource damages and health assessment costs.[7]

Section 108(b) establishes authority to require owners and operators of classes of facilities to establish and maintain evidence of financial responsibility. Section 108(b)(1) directs EPA to develop regulations requiring owners and operators of facilities to establish evidence of financial responsibility ''consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances.'' In turn, section 108(b)(2) directs that the level of financial responsibility shall be initially established, and, when necessary, adjusted to protect against the level of risk that EPA in its discretion believes is appropriate based on the payment experience of the Fund, commercial insurers, court settlements and judgments, and voluntary claims satisfaction. Section 108(b)(2) does not, however, preclude EPA from considering other factors in addition to those specifically listed. The statute prohibited promulgation of such regulations before December 1985.

In addition, Section 108(b)(1) provides for publication within three years of the date of enactment of CERCLA a ''priority notice'' identifying the classes of facilities for which EPA would first develop financial responsibility requirements. It also directs that priority in the development of requirements shall be accorded to those classes of facilities, owners, and operators that present the highest level of risk of injury.

B. History of Section 108(b) Rulemakings

1. 2009 Identification of Priority Classes of Facilities for Development of CERCLA Section 108(b) Financial Responsibility Requirements

On March 11, 2008, Sierra Club, Great Basin Resource Watch, Amigos Bravos, and Idaho Conservation League filed suit in the U.S. District Court for the Northern District of California against then EPA Administrator Stephen Johnson and then Secretary of the U.S. Department of Transportation Mary E.

[3] Although Congress conferred the authority for administering CERCLA on the President, most of that authority has since been delegated to EPA. *See* Exec. Order No. 12580, 52 FR 2923 (Jan. 23, 1987). The executive order also delegates to other Federal agencies specified CERCLA response authorities at certain facilities under those agencies' ''jurisdiction, custody or control.''

[4] CERCLA section 106 authority is also delegated to other Federal agencies in certain circumstances. *See* Exec. Order No. 13016, 61 FR 45871 (Aug. 28, 1996).

[5] S. Rept. 96–848 (2d Sess, 96th Cong.), at 92.

[6] CERCLA section 107(a)(4)(A).

[7] CERCLA section 107(a)(4)(C)–(D).

Peters. *Sierra Club, et al.* v. *Johnson,* No. 08–01409 (N. D. Cal.). On February 25, 2009, that court ordered EPA to publish the Priority Notice required by CERCLA section 108(b)(1) later that year. The 2009 Priority Notice and supporting documentation presented the Agency's conclusion that hardrock mining facilities would be the first class of facilities for which EPA would issue CERCLA section 108(b) requirements.[8] Additionally, the 2009 Priority Notice stated EPA's view that classes of facilities outside of the hardrock mining industry may warrant the development of financial responsibility requirements.[9] The Agency committed to gather and analyze data on additional classes of facilities and to consider them for possible regulation. The court later dismissed the remaining claims.

2. Additional Classes 2010 Advance Notice of Proposed Rulemaking

On January 6, 2010, EPA published an ANPRM,[10] in which the Agency identified three additional industrial sectors for the development, as necessary, of proposed section 108(b) regulations. To develop the list of additional classes for the 2010 ANPRM, EPA used information from the CERCLA National Priorities List (NPL) and analyzed data from the Resource Conservation and Recovery Act (RCRA) Biennial Report and the Toxics Release Inventory created under the Emergency Planning and Community Right-to-Know Act (EPCRA).

3. 2014 Petition for Writ of Mandamus

In August 2014, the Idaho Conservation League, Earthworks, Sierra Club, Amigos Bravos, Great Basin Resource Watch, and Communities for a Better Environment filed a new lawsuit in the U.S. Court of Appeals for the District of Columbia Circuit, seeking a writ of mandamus requiring issuance of CERCLA section 108(b) financial assurance rules for the hardrock mining industry and for three other industries: Electric power generation, transmission, and distribution; petroleum and coal products manufacturing; and chemical manufacturing. Thirteen companies and organizations representing business interests in the hardrock mining and other sectors sought to intervene in the case.

Following oral argument, the court issued an order in May 2015 requiring the parties to submit, among other things, supplemental submissions addressing a schedule for further administrative proceedings under CERCLA section 108(b). Petitioners and EPA requested an order from the court with a schedule calling for the Agency to sign a proposed rule for the hardrock mining industry by December 1, 2016, and a final rulemaking by December 1, 2017. The joint motion also included a requested schedule for the additional industry classes, which called for EPA to sign by December 1, 2016, a determination on whether EPA would issue a notice of proposed rulemaking for classes of facilities in any or all of the other industries, and a schedule for proposed and final rulemakings for the additional industry classes as follows:

EPA will sign for publication in the **Federal Register** a notice of proposed rulemaking in the first additional industry by July 2, 2019, and sign for publication in the **Federal Register** a notice of its final action by December 2, 2020.

EPA will sign for publication in the **Federal Register** a notice of proposed rulemaking in the second additional industry by December 4, 2019, and sign for publication in the **Federal Register** a notice of its final action by December 1, 2021.

EPA will sign for publication in the **Federal Register** a notice of proposed rulemaking in the third additional industry by December 1, 2022, and sign for publication in the **Federal Register** a notice of its final action by December 4, 2024.[11]

While the joint motion identified the three additional industries as the chemical manufacturing industry, the petroleum and coal products manufacturing industry, and the electric power generation, transmission and distribution industry, and set a rulemaking schedule, the motion did not indicate which industry would be the first, second or third. The joint motion specified that it did not alter the Agency's discretion as provided by CERCLA and administrative law.[12]

On January 29, 2016, the court granted the joint motion and issued an order that mirrored the submitted schedule in substance. The order did not mandate any specific outcome of the rulemakings.[13] The Agency has met the deadlines for all three proposed rulemakings, and today's document meets the requirement for announcing final actions on all three additional industry classes.

4. Additional Classes 2017 Notice of Intent To Proceed With Rulemakings

Consistent with the January 2016 court order, EPA signed on December 1, 2016, a determination regarding rulemakings for the additional classes—a Notice of Intent to Proceed with Rulemakings for all three of the additional industry classes. The document was published in the **Federal Register** on January 11, 2017.[14]

The document formally announced EPA's intention to move forward with the regulatory process and to publish a notice of proposed rulemaking for classes of facilities within the three industries identified in the 2010 ANPRM. The announcement in the document was not a determination that requirements were necessary for any or all of the classes of facilities within the three industries, or that EPA would propose such requirements. In addition, the document gave an overview of some of the comments received on the 2010 ANPRM and initial responses to those comments. The comments on the ANPRM which specifically addressed the need for CERCLA section 108(b) requirements for the three additional classes fell into four categories: (1) Other laws with which the industry complies that obviate the need for CERCLA section 108(b) regulation; (2) the sources of data that EPA used to select the industries; (3) past versus current practices within each industry; and (4) the overall need for financial responsibility for each industry. In discussing the ANPRM comments in the 2017 document, the Agency stated its intent to use other, more industry-specific and more current sources of data to identify risk; to consider site factors that reduce risks, including those that result from compliance with other regulatory requirements; and to develop a regulatory proposal for each rulemaking.

At the time of the 2017 document, EPA had not identified sufficient evidence to determine that the rulemaking was not warranted, nor had EPA identified sufficient evidence to establish CERCLA section 108(b) requirements. The document described a process to gather and analyze additional information to support the Agency's ultimate decision, including further evaluation of the classes of facilities within the three industry sectors. The document stated that EPA would decide whether proposing

[8] 74 FR 37214 (July 28, 2009).

[9] *Id.* at 37218.

[10] 75 FR 816 (Jan. 6, 2010).

[11] *In re Idaho Conservation League,* No. 14–1149 (D.C. Cir. Jan. 29, 2016) (order granting joint motion).

[12] *See* Joint Motion at 6 (''Nothing in this Joint Motion should be construed to limit or modify the discretion accorded EPA by CERCLA or the general principles of administrative law.'').

[13] In granting the Joint Motion, the court expressly stated that its order ''merely requires that EPA conduct a rulemaking and then decide whether to promulgate a new rule—the content of which is not in any way dictated by the [order].'' *In re Idaho Conservation League,* at 17 (quoting *Defenders of Wildlife* v. *Perciasepe,* 714 F.3d 1317, 1324 (D.C. Cir. 2013)).

[14] 82 FR 3512 (Jan. 11, 2017).

requirements was necessary and, accordingly, that EPA would propose appropriate requirements or would propose not to impose requirements.

5. The Hardrock Mining Proposal and Final Rulemaking

a. Proposed Rule

On January 11, 2017, EPA proposed requirements in a new 40 CFR part 320 that owners and operators of hardrock mining facilities subject to the rule demonstrate and maintain financial responsibility as specified in the proposed rule. The proposed rule identified two goals for section 108(b) regulations—the goal of providing funds to address CERCLA liabilities at sites, and the goal of creating incentives for sound practices that will minimize the likelihood of need for a future CERCLA response. The proposed rule explained that first, when releases of hazardous substances occur, or when a threat of release of hazardous substances must be averted, a Superfund response action may be necessary. Therefore, the costs of such response actions can fall to the taxpayer if parties responsible for the release or potential release of hazardous substances are unable to assume the costs. Second, the likelihood of a CERCLA response action being needed, as well as the costs of such a response action, are likely to be higher where protective management practices were not utilized during facility operations. The proposed rule discussed information assembled by EPA in the record for the action, which included information on legacy practices and legacy contamination, as well as information not related to risk. Based on that record, EPA had proposed to presume that hardrock mining facilities as a class present the type of risks that section 108(b) addresses. The proposed rule then proceeded to establish a methodology to determine a level of financial responsibility in accordance with a proposed formula. The formula then allowed adjustments to the level of those requirements if a facility could demonstrate site specific conditions that rebut the presumption that the hardrock mining facilities that would be regulated under the rule pose a risk. EPA proposed limiting the applicability of the rule to owners and operators of facilities that are authorized to operate or should be authorized to operate on the effective date of the rule (hereinafter referred to as ''current hardrock mining operations''). The proposed rule relied, in part, on the grounds that these owners and operators are more likely to further the regulatory goals of section 108(b) requirements than are owners and operators of facilities that are closed or abandoned. EPA also proposed limiting the applicability of the rule to current hardrock mining operations because those facilities are readily identifiable and, since they are ongoing concerns, they are more likely to be able to obtain the kind of financial responsibility necessary under the regulation.[15]

b. Decision To Not Impose Requirements

On February 21, 2018, EPA issued its final section 108(b) rule for the hardrock mining industry, concluding that it was not appropriate to establish financial responsibility requirements on this class of facilities. The Agency stated that despite its focus on currently operating facilities, the proposed rule relied on a record of releases of hazardous substances from facilities and payments to respond to such releases that did not present the same risk profile as the facilities operating under modern conditions to which the rule would apply. These modern conditions, the Agency stated, include state and federal regulatory requirements and financial responsibility requirements that currently apply to operating facilities. As a result, EPA determined that the analysis of risk presented in the proposed rule was inconsistent with the scope of the proposed rule and EPA's intended approach under the statute. The final rulemaking did not seek to rely on historical practices, many of which would be illegal under current environmental laws and regulations, to identify the degree and duration of risk posed by the facilities that would be subject to financial responsibility requirements. Instead, in the final rulemaking EPA considered modern federal and state regulation of hazardous substance production, transportation, treatment, storage, or disposal at hardrock mining facilities. EPA concluded the record did not document significant risks associated with such facilities. Further, the final rulemaking did not rely on the cost of responding to historic mining activities and instead reflected the reduction in the risk of federally financed response actions at modern hardrock mining facilities that result from modern practices and modern regulation. EPA concluded that the record demonstrated that, with a few exceptions, EPA had made minimal Fund expenditures for modern hardrock mining operations. EPA also engaged in significant discussions with, and received significant comments from, commercial insurers and other financial instrument providers. These providers suggested that the availability of financial responsibility instruments in the form and amount proposed by EPA may be limited for regulated entities, should EPA require companies to obtain them. Thus, to the extent that risks remain at current hardrock mining operations, the information provided by commenters further convinced EPA that it was not appropriate to establish financial responsibility requirements on this class of facilities. EPA also concluded that issuing final financial responsibility requirements was not necessary to achieve the stated goals of the proposed section 108(b) rules for hardrock mining, namely, the goal to increase the likelihood that regulated entities will provide funds necessary to address CERCLA liabilities if and when they arise, and the goal to create an incentive for sound practices. EPA's economic analysis showing that the proposed rule would avoid governmental costs of only $15–$15.5 million a year supported that conclusion. Based on these estimates, commenters objected that the projected annualized costs to industry ($111–$171 million) were an order of magnitude higher than the avoided costs to the government ($15–15.5 million) sought by the proposed rule. Further, given the fact that federal and state laws, including potential liability under CERCLA, already created incentives for sound practices, promulgating additional financial responsibility regulations for hardrock mining facilities under Section 108(b) also was not necessary to advance that goal.

c. Litigation and D.C. Circuit Decision

After publication of the final section 108(b) rule for hardrock mining facilities, Environmental groups timely filed a petition for review challenging the final rulemaking, asserting that: (1) EPA's statutory interpretation was incorrect, (2) EPA's decision was arbitrary and capricious, and (3) the promulgated final action was not a logical outgrowth of the proposal.[16] On July 19, 2019, the D.C. Circuit upheld EPA's regulatory action and denied the petition for review.[17]

With respect to EPA's statutory interpretation of section 108(b), the court rejected the Petitioners' argument that EPA had misinterpreted ''risk'' in 108(b) as limited to financial risk. The court explained that, typically, a word repeated in different parts of a single

[15] 82 FR 3388–3512 (January 11, 2017).

[16] *Idaho Conservation League, et al.* v. *EPA,* No. 18–1141 (D.C. Cir., filed May 16, 2018).

[17] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494 (D.C. Cir. 2019).

provision has the same meaning throughout that provision, but it can have different meanings if the relevant subject-matter or conditions are different. *See, Weaver* v. *U.S. Info. Agency,* 87 F.3d 1429, 1437 (D.C. Cir. 1996). The court noted that while the prioritization clause of Section 108(b)(1) refers to risk to human health and the environment, the scope of ''risk'' is ambiguous in the general mandate of section 108(b)(1) and the amount clause of section 108(b)(2). In light of the differences among the three clauses, the court held that EPA reasonably interpreted ''risk'' in the latter two clauses to relate only to financial risks.[18]

The court also disagreed with the Petitioners' argument that the mandatory language of section 108(b) required EPA to set financial responsibility requirements for the hardrock mining industry. While the court acknowledged that section 108(b) says that EPA ''shall'' set requirements for certain classes of facilities, the statute gives EPA discretion to determine which classes of facilities to regulate.[19]

Lastly, the court rejected the Petitioners' argument that EPA had failed to account adequately for risks to health and the environment. The court dispensed with this claim, having decided earlier that EPA had reasonably interpreted ''risk'' in the two relevant clauses of section 108(b) to relate only to financial risk of Fund expenditures.[20]

The court also rejected Petitioners' argument that EPA ignored some financial risks and relied on faulty economic analysis. The court concluded that EPA had analyzed the appropriate financial considerations, and the court found no ''serious flaw'' in EPA's economic analysis.[21]

IV. Statutory Interpretation

EPA's statutory interpretation, upheld by the D.C. Circuit as described above, provided the basis for the analytic approach followed in the hardrock mining final rule and subsequently used in the proposals being finalized in this document. EPA is reiterating the statutory interpretation presented in the CERCLA section 108(b) Hardrock Mining Final Rule, and does not intend to reopen this interpretation. The analyses relied upon in the rulemakings that are the subject of today's document were consistent with this statutory interpretation.

CERCLA section 108(b) provides general instructions on how to determine what financial responsibility requirements to impose for a particular class of facility. Section 108(b)(1) directs EPA to develop regulations requiring owners and operators of facilities to establish evidence of financial responsibility ''consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances.'' Section 108(b)(2) directs that the ''level of financial responsibility shall be initially established and, when necessary, adjusted to protect against the level of risk'' that EPA ''believes is appropriate based on the payment experience of the Fund, commercial insurers, courts settlements and judgments, and voluntary claims satisfaction.'' EPA interprets the risk to be addressed by financial responsibility under section 108(b) as the risk of the need for taxpayer-financed response actions. Read together, the statutory language on determining the degree and duration of risk and on setting the level of financial responsibility confers a significant amount of discretion on EPA.

Section 108(b)(1) directs EPA to evaluate risk from a selected class of facilities, but it does not suggest that a precise calculation of risk is either necessary or feasible. Although the cost of response associated with a particular site can be ascertained only once a response action is required, any financial responsibility requirements imposed under section 108(b) would be imposed before any such response action was identified. The statute thus necessarily confers on EPA wide latitude to determine, in a section 108(b) rulemaking proceeding, what degree and duration of risk are presented by the identified class.

Section 108(b)(2) directs EPA to establish the level of financial responsibility that EPA in its discretion believes is appropriate to protect against the risk. This statutory direction does not specify a methodology for the evaluation. Rather, this decision is committed to the discretion of the EPA Administrator. While the statute provides a list of information sources on which EPA is to base its decision—the payment experience of the Superfund, commercial insurers, courts settlements and judgments, and voluntary claims satisfaction—the statute does not indicate that this list of factors is exclusive, nor does it specify how the information from these sources is to be used, such as by indicating how these categories are to be weighted relative to one another.

EPA believes that sections 108(b)(1) and (b)(2) are sufficiently interrelated that it is appropriate to evaluate the degree and duration of risk under subsection (b)(1) by considering the factors enumerated in subsection (b)(2). EPA therefore concludes that Congress intended the risk associated with a particular class of facilities to mean the risk of future Fund-financed cleanup actions in that industry. This reading is supported by the structure of the statute, as section 108(b) appears between two provisions, Sections 108(a) and 108(c), related to cost recovery. Section 108(a), concerning financial assurance requirements for certain vessels, refers specifically to cleanup costs. And section 108(c), concerning recovery of costs from guarantors who provide the financial responsibility instruments, refers specifically to liability for cleanup costs. EPA thus reads ''risk'' in the general mandate of section 108(b)(1) and in the amount clause of section 108(b)(2) consistent with its meaning in sections 108(a) and (c); that is, the risk of Fund-financed cleanup. EPA adopted this interpretation in assessing the need for financial responsibility requirements under CERCLA section 108(b) for facilities in the first class of facilities it evaluated: the hardrock mining industry.[22] In its opinion deciding the challenge to the final action for the hardrock mining industry, the U.S. Court of Appeals for the District of Columbia Circuit held that EPA's interpretation that the provisions of section 108(b) ''relate only to ensuring against financial risks associated with cleanup costs,'' is reasonable and entitled to deference.[23]

For the additional industry classes, EPA has investigated the payment history of the Fund, and enforcement settlements and judgments, to evaluate, in the context of these CERCLA section 108(b) rulemakings, the risk of a Fund-financed response action at facilities that would be subject to CERCLA financial responsibility requirements. The statute also authorizes EPA to consider the existence of federal and state regulatory requirements, including any financial responsibility requirements. Section 108(b)(1) directs EPA to promulgate financial responsibility requirements ''in addition to those under subtitle C of the Solid Waste Disposal Act and other Federal law.'' According to the 1980 Senate Report on legislation that was later enacted as CERCLA, Congress considered it appropriate for EPA to

[18] *Id.* at 502–504.

[19] *Id.* at 504–505.

[20] *Id.* at 505.

[21] *Id.* at 505–508.

[22] 83 FR 7556, 7561–62 (Feb. 21, 2018).

[23] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494, 504 (D.C. Cir. July 19, 2019).

examine those additional requirements when evaluating the degree and duration of risk under the language that was later enacted as CERCLA section 108(b):

> The bill requires also that facilities maintain evidence of financial responsibility consistent with the degree and duration of risks associated with the production, transportation, treatment, storage, and disposal of hazardous substances. These requirements are in addition to the financial responsibility requirements promulgated under the authority of Section 3004(6) of the Solid Waste Disposal Act. It is not the intention of the Committee that operators of facilities covered by Section 3004(6) of that Act be subject to two financial responsibility requirements for the same dangers.[24]

While the Senate Report mentions RCRA Section 3004(6) specifically, it is consistent with congressional intent for EPA to consider other potentially duplicative federal financial responsibility requirements when examining the ''degree and duration of risk'' in the context of CERCLA Section 108(b) to determine whether and what financial responsibility requirements are appropriate. It is also consistent with congressional intent for EPA to consider state laws before imposing additional federal financial responsibility requirements.

Consideration of state laws *before* developing financial responsibility regulations is consistent with CERCLA Section 114(d), which prevents states from imposing financial responsibility requirements for liability for releases of the same hazardous substances *after* a facility is regulated under Section 108 of CERCLA. Just as Congress intended to prevent states from imposing duplicative financial assurance requirements after EPA had acted to impose such requirements under Section 108, it is reasonable to also conclude that Congress did not mean for EPA to disrupt existing state programs that are successfully regulating industrial operations to minimize risk, including the risk of taxpayer liability for response actions under CERCLA, and that specifically include appropriate financial assurance requirements under state law. Reviews of both state programs and other federal programs help to identify whether and at what level there is current risk that is appropriate to address under CERCLA Section 108.

EPA also believes that, when evaluating whether and at what level it is appropriate to require evidence of financial responsibility, EPA should examine information on facilities in the subject universes operating under modern conditions. In other words, EPA should assess the types of facilities to which any new financial responsibility regulations would apply. Financial responsibility requirements under Section 108(b) would not apply to legacy operations that are no longer operating. Rather, any requirements would apply to facilities that follow current industry practices and are subject to the modern regulatory framework (*i.e.,* the regulations currently in place that apply to the industry). These modern conditions include federal and state regulatory requirements and financial responsibility requirements that currently apply to operating facilities. This reading of Section 108(b) is consistent with statements in the legislative history of the statute. The 1980 Senate Report states that the legislative language that became Section 108(b) ''requires those engaged in businesses involving hazardous substances to maintain evidence of financial responsibility commensurate with the risk which they present.''[25] This approach is also consistent with the analysis that EPA undertook, in developing its Final Action on Financial Responsibility Requirements Under CERCLA Section 108(b) for Classes of Facilities in the Hardrock Mining Industry.[26] As described above in section III.B.5.c, EPA's approach was upheld by the U.S. Court of Appeals for the District of Columbia Circuit.[27]

This statutory interpretation is also reflected in today's final actions. Any financial responsibility requirements imposed under Section 108(b) would apply to currently operating facilities. EPA thus sought to examine the extent to which hazardous substance management at currently operating facilities, as three individual classes, continues to present risk. Moreover, the statutory direction to identify requirements consistent with identified risks guides EPA's interpretation that imposition of financial responsibility requirements under Section 108(b) would not be necessary for currently operating facilities that present minimal current risk of a Fund-financed response action. The interpretation in this proposal does not extend to any site-specific determinations of risk made in the context of individual CERCLA site responses. Those decisions will continue to be made in accordance with preexisting procedures.

As the basis for EPA's proposed and final rulemakings, EPA has examined records of releases of hazardous substances from facilities operating under a modern regulatory framework and data on the actions taken and expenditures incurred in response to such releases. The data collected do not reflect historical practices, many of which would be illegal under current environmental laws and regulations. Instead, EPA has considered current federal and state regulation of hazardous substance production, transportation, treatment, storage, or disposal applicable to facilities in the electric power generation, transmission and distribution industry; the petroleum and coal products manufacturing industry; and the chemical manufacturing industry.

V. Electric Power Generation, Transmission and Distribution Industry

A. Proposed Rule

On July 29, 2019, EPA published a notice of proposed rulemaking (NPRM) on the first of the three additional industries.[28] In that document, the Agency proposed to not impose financial responsibility requirements for the electric power generation, transmission, and distribution industry and described the analyses and results that were used to reach that decision.[29] The Agency received 27 comments on this proposed rulemaking. Comments received on the proposal and the Agency's responses are laid out in the Response to Comments document found in the docket to this final rulemaking.[30]

B. Summary of Key Comments Received and Agency Response

Of the 27 comments received on the July 19, 2019 NPRM, 12 were in support of the Agency's proposal to not impose financial responsibility requirements for the electric power generation, transmission, and distribution industry and 15 were opposed.

1. Comments in Support of the Proposal

Seven of the comments the Agency received that supported the proposed rule were from companies in the electric utility industry. In addition, supporting comments were received from the Utility Solid Waste Activities Group, the Superfund Settlements Project, the American Coal Council, the National Mining Association, and a multi-

[24] S. Rept. 96–848 (2d Sess, 96th Cong.), at 92.

[25] S. Rept. 96–848 (2d Sess, 96th Cong.), at 92.

[26] 83 FR 7556 (Feb. 21, 2018).

[27] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494 (D.C. Cir. 2019).

[28] 84 FR 36535 (Jul. 29, 2019).

[29] 84 FR 36535 (July 29, 2019).

[30] *Response to Comments Document: Financial Responsibility Requirement Under CERCLA 108(b) for Classes of Facilities in the Electric Power Generation, Transmission, and Generation Industry, November, 2020.*

industry comment from the U.S. Chamber of Commerce.

Commenters commended EPA for its consistency in the application of its analysis and methodology from the hardrock mining final action to the electric power generation, transmission and distribution industry. Commenters expressed that EPA had appropriately evaluated the risk of the industry and agreed that modern voluntary industry practices and existing federal and state regulations provide an effective framework for risk minimization. Thus, they found the conclusion that additional financial responsibility requirements were not warranted to be reasonable and encouraged the Agency to finalize the decision.

2. Comments Opposed to the Proposal

Twelve of the comments the Agency received that were opposed to the proposed rule were from private citizens. The commenters were concerned that the electric power generation, transmission, and distribution industry should be held accountable for environmental damages that resulted from their actions. Several commenters mentioned wildfires that occurred in California in 2018. It should be noted that the Agency's decision to not impose financial responsibility requirements under Section 108(b) does not diminish liability under CERCLA, and the cost of cleanups will continue to be the responsibility of the PRPs, not the Fund. In addition, comments opposing the proposed rule were received from Earthjustice, the Human Rights Watch, and the Chickaloon Village Traditional Council. Earthjustice submitted comments on behalf of Sierra Club, Earthworks, Environmental Integrity Project, and Western Organization of Resource Councils.

Many of the comments received on the electric power generation, transmission and distribution industry proposal were critical of the Agency's interpretation of the statute and the analyses EPA conducted to conclude that no CERCLA Section 108(b) financial responsibility rules are appropriate. The statutory interpretation presented in the CERCLA Section 108(b) Hardrock Mining Final Rule (described in *Statutory Interpretation* section above) continues to be the view of the Agency, and that interpretation is not reopened here. After consideration of the critical comments, EPA still concludes that the analyses conducted and information considered were appropriate, consistent with CERCLA, and show that risk posed by the electric power generation, transmission and distribution industry does not warrant financial responsibility requirements under CERCLA Section 108(b).

As part of its electric power generation, transmission and distribution industry proposal, EPA systematically evaluated CERCLA NPL, Superfund Alternative Approach (SAA), and removal sites and Coal Combustion Residuals (CCR) damage cases in the industry where cleanup actions and releases occurred. Specifically, EPA developed an analytic approach that considered cleanup cases to identify risk at currently operating facilities and where taxpayer funds were expended for response action. See discussion in the proposed rule [31] for a detailed description of the analysis conducted. EPA's review of the Superfund NPL, SAA, and removal sites associated with the industry, and CCR damage cases identified as part of the 2015 CCR rule, found that, overwhelmingly, the industry was operating responsibly within the current modern regulatory framework. In fact, EPA's analysis determined that only two facilities in the industry had releases under the modern regulatory framework that required a Fund-financed response action. As a matter of due diligence, EPA conducted additional research into instances of releases or accidents at facilities in the industry cited in comments on the proposal. This additional research did not identify any new examples of the Superfund program bearing the costs of a cleanup. In fact, most of the issues were legacy matters from the 1970s and 80s, which the owner or operator of the facility addressed. EPA believes that the small set of federally funded cleanup cases due to recent contamination does not warrant the imposition of financial responsibility requirements on the entire electric power generation, transmission and distribution industry under CERCLA Section 108(b).

Additionally, as part of its proposal, to understand the modern regulatory framework applicable to currently operating facilities within the electric power generation, transmission and distribution industry, EPA compiled applicable federal and state regulations.[32] Specifically, EPA looked to regulations that address the types of releases identified in the cleanup cases. This review also considered industry voluntary programs that could reduce risk of releases. Finally, EPA also identified financial responsibility regulations that apply to facilities in the electric power generation, transmission and distribution industry,[33] and compliance and enforcement history for the relevant regulations.[34] Based on this review, and after reviewing the comments received, EPA maintains its preliminary conclusion that the network of federal and state regulations applicable to the electric power generation, transmission, and distribution industry creates a comprehensive framework that applies to prevent releases that could result in a need for a Fund-financed response action.

As discussed in the July 29, 2019 proposed rule, EPA had developed an analytic approach to determine whether the current risk under a modern regulatory framework within the electric power generation, transmission and distribution industry rose to a level that warrants imposition of financial responsibility requirements under CERCLA Section 108(b).[35] Earthjustice commented that the term ''modern'' is not an objective standard, and that it ''will change any time any new federal or state law is adopted. In effect, under this approach, if a new law is adopted tomorrow, EPA can use that law as a basis for ignoring all relevant evidence, without regard to whether the new law meaningfully addresses the risk of contamination.'' [36] While the Agency agrees the term modern can be subjective, it is used in this case to distinguish the current regulatory landscape versus the one that existed at the time of the passage of the CERCLA statute. Acknowledgment of current federal and state laws that specifically address risks posed by this industry is appropriate to consider in determining whether there is risk of future Fund expenditures. In particular, in the proposal, EPA identified the prevalent sources of risk that were identified in the cleanup cases reviewed. EPA then evaluated the extent to which activities that contributed to the risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances are now regulated. EPA recognized that substantial advances had been made in the development of manufacturing, pollution control, and waste

[31] 84 FR 36535, 36543–36550 (July 29, 2019).

[32] *Summary Report: Federal and State Environmental Regulations and Industry Voluntary Programs in Place to Address CERCLA Hazardous Substances at Facilities in the Electric Power Generation, Transmission and Distribution Industry, June 2019.*

[33] *Review of Existing Financial Responsibility Laws Potentially Applicable to Classes of Facilities in the Electric Power Generation, Transmission, and Distribution Industry, June 2019.*

[34] *Enforcement, Court Settlements and Judgments in the Electric Power Generation, Transmission and Distribution Industry, June 2019.*

[35] 84 FR 36535, 36540 (Jul. 29, 2019).

[36] EPA–HQ–OLEM–2019–0085–0412.

management practices, as well as the implementation of federal and state regulatory programs to both prevent and address such releases at facilities in the electric power generation, transmission, and distribution industry. This analysis is consistent with the approach utilized in the Final Action for Facilities in the Hardrock Mining Industry and upheld by the D.C. Circuit.[37]

Earthjustice also raised the point that the existence of federal and state regulations does not ensure prevention of releases, and that legacy contamination exists at currently operating facilities. EPA notes that financial responsibility requirements under Section 108(b) would not apply to legacy operations that are no longer operating. Rather, any Section 108(b) requirements would apply to facilities that follow current industry practices and are subject to the modern regulatory framework (*i.e.,* the regulations currently in place that apply to the industry). These modern conditions include federal and state regulatory requirements and financial responsibility requirements that currently apply to operating facilities. In contrast to Earthjustice's point, EPA's analysis found that the efficacy of current regulations, as well as voluntary industry practices, while difficult to quantify, have had a demonstrably positive effect in reducing the number of cleanups that require taxpayer expenditures. This was borne out in the analyses conducted in the proposed rule, the results of which indicated that there was no need for further financial responsibility requirements on this industry. An example of an important risk reducing requirement, which targets both legacy and future releases, is the requirement for groundwater monitoring and for corrective action in the 2015 Coal Combustion Residuals rule, for which implementation is ongoing.[38] EPA's 2015 CCR Rule established a first-ever comprehensive set of minimum requirements for the management and disposal of coal ash in landfills and surface impoundments. Among the key requirements included in the rule were structural integrity criteria for CCR surface impoundments, such as periodic hazard potential classification assessments, development of an Emergency Action Plan, periodic structural stability assessments that must document whether the design, construction, operation and maintenance of the unit meets certain stability criteria; periodic safety factor assessments (that must be met or closure will be required); and routine inspections. The rule also required the installation of groundwater monitoring wells and an ongoing groundwater monitoring program designed to detect releases of critical constituents, as well as requirements to clean up any releases. The combination of these requirements and others in the rule have substantially mitigated the risks from these facilities.

The 2015 CCR Rule also established timelines and standards for closure and post-closure care. Specifically, the rule requires all CCR units to close in accordance with specified standards and to monitor and maintain the units for a period of time after closure, including the groundwater monitoring and corrective action programs. These criteria help ensure the long-term safety of closed CCR units.

Earthjustice and Human Rights Watch opposed the Agency's reliance on the *Disposal of Coal Combustion Residuals from Electric Utilities Final Rule* to evaluate risk posed by this industry for two reasons—first, commenters argued, because it has no proven track record, and secondly, the Agency has had to reconsider, on remand, portions of the 2015 rule as a result of the decision in *Utility Solid Waste Activities Group (USWAG) et al.* v. *EPA.*[39] In fact, the *USWAG* decision invalidated only a limited portion of the 2015 rule. Furthermore, the Water Infrastructure Improvements for the Nation Act (WIIN Act) of 2016 has enhanced the program by providing EPA additional authorities. Section 2301 of the WIIN Act amends Section 4005 of RCRA to provide for state CCR permit programs. As a consequence of the D.C. Circuit's decision in *USWAG,* unlined, including clay lined, surface impoundments must cease receipt of waste and initiate closure, which will further reduce risks to human health and the environment. To implement this decision, EPA recently promulgated regulations requiring that unlined surface impoundments and CCR units that fail the aquifer location restriction cease receiving waste and initiate closure by April 11, 2021, unless a facility qualifies for one of two narrow extensions. Further, EPA is working on developing a permit program that will increase the oversight of these facilities. Finally, EPA is diligently working with many states to aid in the development of state CCR permitting programs that are at least as protective as the federal CCR regulations. Before the 2015 CCR Rule was promulgated, states were not required to adopt or implement the regulations or to develop a permit program. It also did not provide a mechanism for EPA to approve a state permit program to operate ''in lieu of'' the federal regulations. The WIIN Act provides EPA the authority to review and approve state CCR permit programs. The Act also allows EPA to develop permits for those units located on tribal lands and, if given specific appropriations, EPA will develop a permitting program for those units located in non-participating states. In addition, EPA must review State permit programs at least once every 12 years and in certain specific situations. The WIIN Act also expands the enforcement authorities available to EPA. EPA may use its information gathering and enforcement authorities under RCRA Sections 3007 and 3008 to enforce the 2015 CCR Rule or permit provisions. All of these actions will further ensure that CCR units are properly regulated to protect human health and the environment. Moreover, EPA notes that the Electric Power sector has generated very few Superfund sites even prior to the 2015 CCR rule.

Earthjustice disagreed with EPA's screening out from its analyses sites where the response actions were funded by private parties as opposed to the government. Earthjustice suggested that it is contrary to CERCLA to focus only on financial risk. In addition, Earthjustice raised concerns about the magnitude and potential long duration of cleanups in the industry, in particular at coal ash facilities.

As a primary matter, EPA's approach and the factors the Agency considered to determine whether or not financial responsibility requirement were appropriate for the electric power generation, transmission, and distribution industry is consistent with CERCLA (see *Statutory Interpretation* section above). A chief factor was the results of EPA's cleanup case analysis which involved a systematic examination of Superfund sites (NPL, removal, SAA) and CCR damage cases. EPA's analysis, described in detail in section VII of the proposed rule,[40] showed that facilities in the sector have not historically burdened the Fund. First, the Agency identified very few NPL sites with pollution associated with the electric power generation, transmission, and distribution industry. Of the only five NPL sites associated with the Electric Power industry

[37] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494, (D.C. Cir. 2019).

[38] Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals From Electric Utilities, 80 FR 21302, Apr. 17, 2015 (''2015 CCR Rule'').

[39] *Utility Solid Waste Activities Group (USWAG) et al.* v. *EPA,* No. 15–1219 (D.C. Cir. Aug. 21, 2018).

[40] 84 FR 36535, 36543 (July 29, 2019).

identified, all were either the product of legacy contamination or had PRP leads conducting the cleanup. The Agency also reviewed 27 CCR damage cases and 24 Superfund removal sites associated with the industry and identified only two removal sites where addressing pollution from a modern operation required Superfund expenditures. This minimal historical fund burden is, in part, due to the fact that the potentially responsible parties (PRPs) led many of the cleanups identified. For example, all of the NPL sites associated with the industry were PRP-led as were all of the CCR damage cases for which cleanup lead information was available. Further supporting this finding is the fact that when a cleanup is required under Superfund or corrective action, financial assurance is typically required. Moreover, as discussed below, EPA conducted additional research into examples of releases at facilities in the electric power generation, transmission, and distribution industry identified by commenters. That additional research did not identify any new examples of the Superfund program bearing the costs of a cleanup. The limited number of actions within the sector, combined with its track record of funding cleanups weighs against the need for regulation under CERCLA Section 108(b).

The comment also intended to suggest that CERCLA Section 108(b) financial responsibility could promote rapid cleanup in instances of pollution. As a primary matter, this is not necessarily the case. EPA believes any CERCLA Section 108(b) financial responsibility required for any industry would complement existing Superfund processes by offering a financial backstop for CERCLA costs and damages (see the relevant language at 84 FR 3400 included in the hardrock mining proposal). The financial responsibility would not modify the existing Superfund enforcement authorities, including those to gather information, identify responsible parties, effect cleanup (especially through EPA's enforcement first policy), assess penalties, or provide for citizen suits. In instances where releases occurred that required a Superfund cleanup the same Superfund process would occur as does today.

Of note is that the Superfund program protects human health and the environment regardless of whether or not financial responsibility is in place. EPA can invoke its enforcement authorities to protect human health and the environment. For example, EPA can issue a Unilateral Administrative Order or conduct a removal action to mitigate potential risks posed by the site conditions. If the Agency has to use fund resources to conduct a cleanup, EPA can take an enforcement action to recover its CERCLA costs and replenish government resources. It is thus not accurate to suggest a lack of CERCLA Section 108(b) financial responsibility would result in delays of cleanup and therefore an increased risk to human health and the environment.

Earthjustice took issue with EPA's interpretation of the statute, stating that EPA's ''interpretation of the statute to focus solely on the risk of a taxpayer bailout of insolvent companies is contrary to law, because this is not the purpose of CERCLA.'' [41] Earthjustice contends that EPA ignored significant risks to human health and the environment. The primary example offered by the commenters was risk to human health and drinking water sources from coal ash. EPA believes that the site analysis for this rulemaking effectively considered human health and environmental risk in multiple steps. First, EPA examined through the Agency's industry practices and environmental characterization analysis the operational practices and environmental profile of the electric power generation, transmission, and distribution industry. This analysis included an examination of the potentially hazardous materials used in the industry, hazardous wastes generated by industry processes, the units used to manage wastes at these sites, how on-site management of these materials can potentially contribute to releases, and what contaminants might be released by the industry that could impact human health and the environment. Next, EPA investigated in what ways the industry is subject to a wide range of modern federal and state regulatory requirements and enforcement oversight imposed to address this potential human health and environment risk. In these analyses, EPA outlined the framework of modern federal and state regulatory programs to which the industry is subject,[42] and also examined compliance and enforcement for the industry,[43] which collectively demonstrate how these components work to address potential risk for modern industry operations. Overall, EPA's full analytic approach developed for the proposed rule examined sites with a variety of contaminants and contaminated media. In effect, the analysis considered the types of human health and environmental risk the Superfund program was designed to address, and that would be addressed by any CERCLA Section 108(b) financial responsibility. This analysis employed by the Agency is consistent with EPA's interpretation of the statutory language and was upheld by the D.C. Circuit,[44] which found that EPA's focus on risk of taxpayer-funded response actions was reasonable. Specifically, the Court stated in its decision, ''we defer to the EPA's interpretation that it should set financial responsibility regulations based on financial risks, not risks to health and the environment.'' [45] EPA's analysis based on this interpretation showed that there is little evidence of the facilities operating under a modern regulatory framework burdening the Fund.

An additional related concern of Earthjustice was that EPA's analysis of the economics of the industry identified risks in certain subsectors of the electric power generation, transmission, and distribution industry and thus, the commenter argues, those subsectors merit regulation under Section 108(b). To further assess these concerns related to the financial risks posed by the industry, EPA updated its analysis supporting the Economic Sector Profile originally conducted in support of the proposed rulemaking. This updated analysis finds the financial stability of the industry relatively unchanged from the original report, further suggesting that the economic conditions of the industry as a whole are not at undue risk.[46] Numerous commenters also provided further evidence in response to information presented in the proposed rule regarding the positive economic standing of the electric power generation, transmission, and distribution industry. Commenters attributed the positive economic standing to attributes such as the industry's critical monopolistic commodity, inherent governmental nature and oversight, transparent corporate structures, public service goals, broad adherence to strict accounting standards set forth by the Governmental Accounting Standards

[41] EPA–HQ–OLEM–2019–0085–0412.

[42] *Summary Report: Federal and State Environmental Regulations and Industry Voluntary Programs in Place to Address CERCLA Hazardous Substances at Facilities in the Electric Power Generation, Transmission and Distribution Sector, June 2019.*

[43] *Enforcement, Court Settlements and Judgments in the Electric Power Generation, Transmission and Distribution Industry, June 2019.*

[44] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494 (D.C. Cir. 2019).

[45] *Id.* at 504.

[46] *Addendum Update to CERCLA 108(b) Economic Sector Profile: Electric Power Generation, Transmission, and Distribution Industry, May 2020.*

Board (GASB), and lower relative costs of securing capital.

Some commenters also pointed more specifically to the market decline in coal-fired power generation as a source of particular concern. In both the original Economic Sector Profile and Updated Addendum, EPA acknowledges that this subsector is in a period of transition and on weaker standing compared to the industry overall. However, analyses by the U.S. Energy Information Agency (EIA) forecast that by 2025, the rate of coal plant retirements will stabilize, with steady coal-based generation thereafter over the longer term.[47] Furthermore, characteristics of diversity in terms of organizational structure, ownership type, and energy portfolios are expected to help further stabilize this subsector. Thus, while the subsector may experience a continued decline in capacity and generation levels in the near term, it is forecasted to stabilize and continue to play a material role in electricity generation for decades, even as renewable generation capacity increases significantly. As such, EPA believes that, as with the industry as a whole, the financial stability of this subsector similarly negates the need for regulation under CERCLA Section 108(b).

Also included in the comments were examples of recent accidents and releases at facilities in the electric power generation, transmission, and distribution industry, in particular facilities that manage CCRs. EPA appreciated the comments and undertook additional due diligence to examine some of these releases and accidents referenced by the commenter. While most accidents and releases do not lead to Superfund responses, Fund expenditures, or CERCLA liability claims, and the commenters provided no indication a Superfund response resulted from the incidents in question, EPA acknowledged the possibility that some of these releases and accidents may have required Superfund actions, which the Agency may have missed in the analysis conducted as part of the proposal. As such, EPA examined a selection of the cases referenced by the commenter to better understand the consequences of these incidents, to the extent possible.

In the case of the electric power generation, transmission, and distribution industry proposal, many of the referenced releases were legacy issues which the 2015 CCR rule was designed to address. EPA did not conduct further research into these examples. Likewise, EPA did not conduct further research into accidents and releases referenced by commenters that were already accounted for in the proposed rule. Only a small number of facilities with releases identified by commenters may have represented instances of pollution occurring under a modern regulatory framework resulting in a taxpayer funded Superfund action that were not already accounted for by the EPA proposal. EPA examined these few facilities in greater detail. In all cases, EPA determined that the contamination was a legacy issue stemming from the 1970s and 1980s. Moreover, the pollution was abated, and the owner or operator has or is addressing the issue in all of the cases. As such, EPA does not believe the incidents cited by commenters merit a change in direction from the original proposal. More information on the incidents cited by commenters and researched by EPA is provided in the docket in the spreadsheet titled *NAICS 2211 Incident research* containing the information gathered, information sources considered and summary findings.[48]

C. Decision To Not Impose Requirements

Based on the analyses conducted for the July 29, 2019 proposed rule, described in detail in the background documents for that document, as well as additional analyses conducted in response to comments received on that document, the Agency is finalizing the decision that the degree and duration of risk posed by the electric power generation, transmission and distribution industry does not warrant financial responsibility requirements under CERCLA Section 108(b). As such, this rulemaking will not impose CERCLA Section 108(b) financial responsibility requirements for facilities in the electric power generation, transmission, and distribution industry. EPA did not receive evidence from any commenter that changed the Agency's determination from that proposed previously.

Central to this final rulemaking decision is EPA's position that the analyses conducted for the proposal are consistent with the statutory language of CERCLA Section 108(b), described in Section IV above (*Statutory Interpretation*). EPA is further assured of this position following the decision by the D.C. Circuit that upheld EPA's interpretation of the statutory language of CERCLA Section 108(b).[49] The analyses consistent with this interpretation showed that under the modern regulatory framework that applies to the electric power generation, transmission, and distribution industry, little evidence of burden to the Fund by facilities in this industry exists.

EPA believes that the evaluation of the electric power generation, transmission and distribution industry conclusively demonstrates, by the low occurrence of cleanup sites that significantly impact the Fund, low risk of a Fund-financed response action at current electric power generation, transmission and distribution operations. The reduction in risks, relative to when CERCLA was first established, attributable to the requirements of existing regulatory programs and voluntary practices combined with reduced costs to the taxpayer—demonstrated by EPA's cleanup case analysis, existing financial responsibility requirements, and enforcement actions—has reduced the need for federally-financed response action at facilities in the electric power generation, transmission and distribution industry.

VI. Petroleum and Coal Products Manufacturing Industry

A. Proposed Rule

On December 23, 2019, EPA published a notice of proposed rulemaking (NPRM) on the second of the three additional industries.[50] In that document, the Agency proposed to not impose financial responsibility requirements for the petroleum and coal products manufacturing industry and described the analyses and results that were used to reach that decision. The Agency received 10,381 comments on this proposed rulemaking, of which 10,216 were from a mass mail campaign and 165 comments were unique. Comments received on the proposal and the Agency's responses are laid out in the Response to Comments document found in the docket to this final rulemaking.[51]

B. Summary of Key Comments Received and Agency Response

Of the 165 unique comments received on the December 23, 2019 NPRM, 6 were in support of the Agency's proposal to not impose financial

[47] Annual Energy Outlook 2020 (AEO 2020).

[48] See spreadsheet, in docket for this action, titled ''NAICS 2211_Incident research.xlsx''.

[49] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494 (D.C. Cir. 2019).

[50] 84 FR 70467 (Dec. 23, 2019).

[51] *Response to Comments Document: Financial Responsibility Requirement Under CERCLA 108(b) for Classes of Facilities in the Petroleum and Coal Products Manufacturing Industry, November, 2020.*

responsibility requirements for the petroleum and coal products manufacturing industry and 159 were opposed, which includes 142 comments that were associated with the mass mail campaign and 17 other unique comments.

1. Comments in Support of the Proposal

The Agency received comments from the American Coke and Coal Chemicals Institute, the American Fuel and Petrochemical Manufacturers, the American Petroleum Institute (API), Sun Coke Energy, the Superfund Settlements Project, and a multi-industry comment from the U.S. Chamber of Commerce in support of the proposed rule.

Commenters in support of the proposal said that petroleum refineries are owned by very large and stable companies with superior economic resources, and that modern regulations adequately mitigate risks posed by the industry. One commenter stated that ''of all the petroleum refineries that have closed since 1990, not a single facility has been added to the NPL that required the expenditure of public funds.'' Further, they added that ''legacy sites that have been addressed through Superfund largely operated prior to the implementation of the modern regulatory system and are not representative of today's petroleum refinery operations.'' [52]

In addition, commenters on the petroleum and coal products manufacturing industry proposal positively cited the July 19, 2019 opinion from the D.C. Circuit, as support for the Agency's final action to not impose CERCLA Section 108(b) financial responsibility requirements for facilities in the petroleum and coal products manufacturing industry.[53]

2. Comments Opposed to the Proposal

Of the 159 comments received that were opposed to the proposed rule, 158 were from private citizens, including 142 comments that were associated with the mass mail campaign and 16 other unique comments, and one was from Earthjustice. The comments from private citizens concerned holding petroleum and coal products manufacturers accountable for environmental damages as a result of their actions. Many commenters were under the belief that the Agency was ''rolling back'' existing regulations requiring industry accountability. In fact, this rulemaking does not revoke or reverse any existing regulations. As with the other industries, the Agency's decision to not impose financial responsibility requirements under Section 108(b) does not diminish liability under CERCLA, and the cost of cleanups will continue to be the responsibility of the PRPs, not the Fund. Earthjustice submitted comments on behalf of Communities for a Better Environment, Center for Biological Diversity, Earthworks, Sierra Club, Idaho Conservation League, Amigos Bravos, Great Basin Resource Watch, and Public Citizen.

Many of the comments received on the petroleum and coal products manufacturing industry proposal were critical of the Agency's interpretation of the statute and the analyses EPA conducted to conclude that no CERCLA Section 108(b) financial responsibility rules are necessary. The statutory interpretation presented in the CERCLA Section 108(b) Hardrock Mining Final Rule (described in *Statutory Interpretation* section above) continues to be the view of the Agency, and that interpretation is not reopened here. After consideration of the critical comments, EPA still concludes that the analyses conducted and information considered were appropriate, consistent with CERCLA, and show that risk posed by the petroleum and coal products manufacturing industry does not warrant financial responsibility requirements under CERCLA Section 108(b).

As part of its petroleum and coal products manufacturing industry proposal, EPA systematically evaluated CERCLA NPL, Superfund Alternative Approach (SAA), and removal sites in the industry where releases and cleanup actions occurred. Specifically, EPA developed an analytic approach that considered cleanup cases to identify risk at currently operating facilities and where taxpayer funds were expended for response action. See discussion in the proposed rule [54] for a detailed description of the analysis conducted. EPA's review of the Superfund NPL, SAA, and removal sites associated with the industry found that, overwhelmingly, the industry was practicing responsibly within the current regulatory framework, with just one site indicating a significant impact to the Fund while operating under the modern regulatory framework. EPA described this site in detail in the Removals Site Analysis background document to the proposal.[55] EPA believes that the small set of federally funded cleanup cases due to recent contamination does not warrant the imposition of costly financial responsibility requirements on the entire petroleum and coal products manufacturing industry under CERCLA Section 108(b).

Additionally, as part of its proposal, to understand the modern regulatory framework applicable to currently operating facilities within the petroleum and coal products manufacturing industry, EPA compiled applicable federal and state regulations.[56] Specifically, EPA looked to regulations that address the types of releases identified in the cleanup cases. This review also considered industry voluntary programs that could reduce risk of releases. Finally, EPA also identified financial responsibility regulations that apply to facilities in the petroleum and coal products manufacturing industry,[57] and compliance and enforcement history for the relevant regulations.[58] Based on this review, and after reviewing the comments received, EPA maintains its preliminary conclusion that the network of federal and state regulations applicable to the petroleum and coal products manufacturing industry creates a comprehensive framework that applies to prevent releases that could result in a need for a Fund-financed response action.

As discussed in the December 23, 2019 proposed rule, EPA had developed an analytic approach to determine whether the current risk under a modern regulatory framework within the petroleum and coal products manufacturing industry rose to a level that warrants imposition of financial responsibility requirements under CERCLA Section 108(b).[59] Earthjustice commented that relying on the term ''modern'' is EPA's ''basis for ignoring significant evidence of risk.'' [60] The Agency uses the term modern in this case to distinguish the current regulatory landscape versus the one that existed at the time of the passage of the CERCLA statute. Acknowledgment of

[52] EPA–HQ–OLEM–2019–0087–0468.

[53] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494 (D.C. Cir. 2019).

[54] 84 FR 70475–70482.

[55] *Identification and Evaluation of CERCLA 108(b) Petroleum and Coal Products Manufacturing non-National Priorities List (NPL) Removal Sites.*

[56] *Summary Report: Federal and State Environmental Regulations and Industry Voluntary Programs in Place to Address CERCLA Hazardous Substances at Petroleum Refineries and Other Petroleum and Coal Products Manufacturing Facilities.*

[57] *Review of Existing Financial Responsibility Laws Potentially Applicable to Classes of Facilities in the Petroleum and Coal Products Manufacturing Industry.*

[58] *Enforcement, Court Settlements and Judgments in the Petroleum and Coal Products Manufacturing Industry.*

[59] 84 FR 36540 (Jul. 29, 2019).

[60] EPA–HQ–OLEM–2019–0087–0474.

current federal and state laws that specifically address risks posed by this industry is appropriate to consider in determining whether there is risk of future Fund expenditures. In particular, in the proposal, EPA identified the prevalent sources of risk that were identified in the cleanup cases reviewed. EPA then evaluated the extent to which activities that contributed to the risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances are now regulated. EPA recognized that substantial advances had been made in the development of manufacturing, pollution control, and waste management practices, as well as the implementation of federal and state regulatory programs to both prevent and address such releases at facilities in the petroleum and coal products manufacturing industry. This analysis is consistent with the approach utilized in the Final Action for Facilities in the Hardrock Mining Industry and upheld by the D.C. Circuit.[61]

Earthjustice also raised the point that the existence of federal and state regulations does not ensure prevention of releases, and that legacy contamination exists at currently operating facilities. EPA notes that financial responsibility requirements under Section 108(b) would not apply to legacy operations that are no longer operating. Rather, any Section 108(b) requirements would apply to facilities that follow current industry practices and are subject to the modern regulatory framework (*i.e.,* the regulations currently in place that apply to the industry). These modern conditions include federal and state regulatory requirements and financial responsibility requirements that currently apply to operating facilities. In contrast to Earthjustice's point, EPA's analysis found that the efficacy of current regulations, as well as voluntary industry practices, while difficult to quantify, have had a demonstrably positive effect in reducing the number of cleanups that require taxpayer expenditures. This was borne out in the analyses conducted in the proposed rule, the results of which indicated that there was no need for further financial responsibility requirements on this industry.

Earthjustice disagreed with EPA's screening out from its analyses sites where the response actions were funded by private parties as opposed to the government. Earthjustice suggested that it is contrary to CERCLA to focus only on financial risk. In addition, Earthjustice raised concerns about the magnitude and potential long duration of cleanups in the industry.

As a primary matter, EPA's approach and the factors the Agency considered to determine whether or not financial responsibility requirements were appropriate for the petroleum and coal products manufacturing industry is consistent with CERCLA (see *Statutory Interpretation* section above). A chief factor was the results of EPA's cleanup case analysis which involved a systematic examination of Superfund sites (NPL, removal, and SAA). EPA's analysis, described in detail in section VII of the proposed rule,[62] showed that facilities in the sector have not historically burdened the Fund in that the Agency identified only one site where pollution from a modern operation required significant Superfund expenditures to address. None of the NPL sites burdened the Fund with pollution that occurred while operating under a modern regulatory framework. This is, in part, due to the fact that the potentially responsible parties (PRPs) led many of the cleanups identified. For example, 19 of the 34 NPL sites associated with the industry were PRP led. Further supporting this finding is the fact that when a cleanup is required under Superfund or corrective action or RCRA, financial assurance is typically required. Moreover, as discussed below, EPA conducted additional research into examples of releases at facilities in the petroleum and coal products manufacturing industry by commenters. That additional research identified only four new examples of the Superfund program bearing the costs of a cleanup. The limited number of actions within the sector, combined with its track record of funding cleanups weighs against the need for regulation under CERCLA Section 108(b).

The comment also intended to suggest that CERCLA Section 108(b) financial responsibility could promote rapid cleanup in instances of pollution. As a primary matter, this is not necessarily the case. EPA believes any CERCLA Section 108(b) financial responsibility required for any industry would complement existing Superfund processes by offering a financial backstop for CERCLA costs and damages (see the relevant language at 84 FR 3400 included in the hardrock mining proposal). The financial responsibility would not modify the existing Superfund enforcement authorities, including those to gather information, identify responsible parties, effect cleanup (especially through EPA's enforcement first policy), assess penalties, or provide for citizen suits. In instances where releases occurred that required a Superfund cleanup, the same Superfund process would occur as does today.

Of note is that the Superfund program protects human health and the environment regardless of whether or not financial responsibility is in place. EPA can invoke its enforcement authorities to protect human health and the environment. For example, EPA can issue a Unilateral Administrative Order or conduct a removal action to mitigate potential risks posed by the site conditions. If the Agency has to use fund resources to conduct a cleanup, EPA can take an enforcement action to recover its CERCLA costs and replenish government resources. It is thus not accurate to suggest a lack of CERCLA Section 108(b) financial responsibility would result in delays of cleanup and therefore an increased risk to human health and the environment.

Earthjustice took issue with EPA's interpretation of the statute, stating that EPA's ''interpretation of the statute to focus solely on the risk of a taxpayer bailout of insolvent companies is contrary to law, because this is not the purpose of CERCLA.'' [63] Earthjustice contends that EPA ignored significant risks to human health and the environment. Specifically, the comment stated the Agency ignored vast amounts of data that links large oil refineries to toxic pollutants contaminating drinking water. EPA believes that the site analysis for this rulemaking effectively considered human health and environmental risk in multiple steps. First, EPA examined through the Agency's industry practices and environmental characterization analysis the operational practices and environmental profile of the petroleum and coal products manufacturing industry. This analysis included an examination of the potentially hazardous materials used in the industry, hazardous wastes generated by industry processes, the units used to manage wastes at these sites, how on-site management of these materials can potentially contribute to releases, and what contaminants might be released by the industry that could impact human health and the environment. Next, EPA investigated in what ways the industry is subject to a wide range of modern federal and state regulatory requirements and enforcement oversight imposed to address this potential

[61] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494, (D.C. Cir. 2019).

[62] 84 FR 70467, 70475 (Dec. 23, 2019).

[63] Id.

human health and environment risk. In these analyses, EPA outlined the framework of modern federal and state regulatory programs to which the industry is subject,[64] and also examined compliance and enforcement for the industry,[65] which collectively demonstrate how these components work to address potential risk for modern industry operations. Overall, EPA's full analytic approach developed for the proposed rule examined sites with a variety of contaminants and contaminated media. In effect, the analysis considered the types of human health and environmental risk the Superfund program was designed to address, and that would be addressed by any CERCLA Section 108(b) financial responsibility. This analysis employed by the Agency is consistent with EPA's interpretation of the statutory language and was upheld by the D.C. Circuit,[66] which found that EPA's focus on risk of taxpayer-funded response actions was reasonable. Specifically, the Court stated in its decision, ''we defer to the EPA's interpretation that it should set financial responsibility regulations based on financial risks, not risks to health and the environment.'' EPA's analysis based on this interpretation showed that there is little evidence of the facilities operating under a modern regulatory framework burdening the Fund.

Many of the commenters asserted that, too often, companies file for bankruptcy and avoid financial responsibility for cleaning up harmful pollution. To further assess these concerns, EPA updated its analysis supporting the Economic Sector Profile originally conducted in support of the proposed rulemaking. This update was conducted with data available concurrent with the close of comment period for the proposed rule. This updated analysis finds the financial stability of the industry relatively unchanged from the original report, further suggesting that the economic conditions of the industry as a whole are not at undue risk.[67] In addition, no evidence was identified or provided by commenters that EPA could use to determine that companies in this industry were found to have avoided responsibility for cleanup costs that resulted in CERCLA funds being expended.

Also included in comments from Earthjustice were examples of recent accidents and releases at petroleum refineries.[68] EPA appreciated the comments and undertook additional due diligence to examine and analyze some of these releases and accidents referenced by the commenter. While most accidents and releases do not lead to Superfund responses, Fund expenditures, or CERCLA liability claims, and the commenters provided no indication a Superfund response resulted from the incidents in question, EPA acknowledged that it is possible some of these releases and accidents may have required Superfund actions which the Agency may have missed in the analysis conducted as part of the proposal. As such, EPA examined a selection of the cases referenced by Earthjustice to better understand the consequences of these incidents, to the extent possible.

In the case of the petroleum and coal products manufacturing industry proposal, the selection criteria were based on whether or not releases to land or water were indicated, whether or not data were available, and whether or not the facility was already in the Agency's record. Many of the referenced releases were in the form of data sets of compiled releases. In some cases, there was insufficient information for EPA to identify the underlying data sources or names of specific facilities and thus EPA was unable to conduct further research into those incidents. One specific site referenced, the Oklahoma Refining Company site, was already included in the NPL sites reviewed as part of the proposal and thus was not investigated further. In that case, the contamination at the site was the result of legacy practices that pre-dated RCRA and many other environmental protections. Finally, EPA did not conduct additional investigation into specific incidents of flaring identified by the commenter at refineries, as the practice is actually a common safety practice and highly unlikely to require a response action.

In addition to the facilities selected for research using the above criteria, EPA was able to conduct additional research on a sample of 20 sites provided in a data set from the California Office of Emergency Services referenced by the commenter. In total, EPA conducted research into 43 petroleum and coal products manufacturing facilities with releases or accidents identified by commenters that may have represented instances of pollution occurring under a modern regulatory framework resulting in a taxpayer funded Superfund action.

Generally, the incidents EPA researched fell into three categories: (1) Catastrophic fires, explosions, or environmental releases that endangered worker and community safety and/or caused environmental harm; (2) Clean Water Act, Clean Air Act, and RCRA violations records; and (3) flaring and other minor refinery incidents that were reported to the California Office of Emergency Services. The majority of the information collected about those incidents as part of the supplementary research effort indicated that other primary responders and enforcing agencies (such as the Occupational Safety and Health Administration (OSHA), or state and county agencies) managed the situation, or that it was unclear or unlikely that environmental contamination had occurred as a result of the incident. In total, five of the incidents resulted in EPA response action and/or expenditure. Four of these were removal actions and one an enforcement action. Of these five, the information collected suggests that EPA was able to recover its response costs from the potentially responsible parties (PRPs) at one of the sites. In the remaining four, the EPA Superfund expenditures to date have been minimal. The sites (or incidents, identified by site) and the associated expenditures (listed in parentheses) are the Philadelphia Energy Solutions site in Philadelphia, PA ($85,000), the Husky Refinery in Superior, WI ($200,000), the Chevron Refinery Fire in Richmond, CA ($16,250), and the Caribbean Petroleum Refining Tank Explosion and Fire in Bayamon, PR ($178,295). Recovery of these minimal costs is possible in light of the viable owners and operators at the sites that plan to either redevelop the site or rebuild the facility. For example, at the Philadelphia Energy Solutions site, the current owner operator plans to permanently close the refinery and redevelop the property. A former owner operator is already conducting cleanup of pollution at the site that existed as of 2012 under a 2012 RCRA/CERCLA settlement that includes a financial assurance requirement.[69] Additionally,

[64] *Summary Report: Federal and State Environmental Regulations and Industry Voluntary Programs in Place to Address CERCLA Hazardous Substances at Petroleum Refineries and Other Petroleum and Coal Products Manufacturing Facilities.*

[65] *Enforcement, Court Settlements and Judgments in the Petroleum and Coal Products Manufacturing Industry.*

[66] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494 (D.C. Cir. 2019).

[67] *Addendum Update to CERCLA 108(b) Economic Sector Profile: NAICS 324—Petroleum and Coal Products Manufacturing; May 2020.*

[68] EPA–HQ–OLEM–2019–0087–0474.

[69] *In the matter of Philadelphia Energy Solutions LLC and Philadelphia Energy Solutions Refining and Marketing LLC: Settlement Agreement and Covenant not to Sue.* Docket number CERC/RCRA–03–2012–0224DC (August 17. 2012). Available in

Continued

at two of the sites the owner or operator have agreed to conduct significant environmental work as part of settlements with EPA and other parties. Accordingly, EPA does not believe the incidents cited by commenters merit a change in direction from the proposal.

Moreover, these examples of releases indicated that the modern regulatory framework has robust response and coordination mechanisms in place to respond to such incidents. The major releases triggered responses from a variety of parties including state and federal environmental regulators and state and federal occupational safety responses that undertook appropriate actions (*e.g.,* fines, orders). For example, at the 2007 Valero refinery fire in Sunray, TX, both EPA and the Texas Commission on Environmental Quality (TCEQ) responded to the incident. TCEQ conducted some initial air monitoring and sampling at the site. Valero conducted all other response activities: Fire suppression, asbestos air sampling, wet removal of asbestos debris, air monitoring, neutralization of acid spill, assessment of leaking propane line, and assessment of all units for damage. EPA and TCEQ monitored progress at the facility, but departed the site three days after the fire on account of the situation being stable. More information on the incidents cited by commenters and researched by EPA is provided in the docket in the spreadsheet titled *NAICS 324 Incident research* containing the information gathered, information sources considered and summary findings.[70]

In addition to completing examination of the incidents cited in comments, EPA is also aware of some recent incidents of releases from refinery facilities, for example the ExxonMobil Fire in Baton Rouge, LA. This example exhibits coordinated response of local and federal services that demonstrate the expected performance of the modern regulatory framework. At the ExxonMobil refinery fire, which occurred on Feb. 11, 2020, the Louisiana Department of Environmental Quality (LDEQ) and the Baton Rouge Fire Department (BRFD) Hazmat team responded to the incident and conducted offsite air monitoring. EPA also mobilized a Superfund Technical Assessment & Response Team contractor to the site.[71] ExxonMobil conducted multiple rounds of air monitoring of the facility, and readings were found to be below the state's ambient air standards.[72] At this site, the local authorities were able to respond quickly and in cooperation with the company to ensure that risk was promptly assessed and addressed.

Although this incident was not cited by commenters, and though releases to air as occurred in this example have not been identified as prevalent causes of inclusion of a site on the NPL, EPA offers that the prompt response that took place following this incident illustrates the protective function of the modern regulatory framework. Coordinated responses at petroleum and coal products manufacturing facilities when incidents do occur lessen the likelihood of these facilities becoming Superfund sites, which further weighs against the need for financial responsibility requirements for the petroleum and coal products manufacturing industry under CERCLA Section 108(b). Furthermore, this response demonstrates that authorities already in place to respond to incidents provide state and local entities the tools to take actions that address many of the risks that might result in a Superfund site.

C. Decision To Not Impose Requirements

Based on the analyses conducted for the December 23, 2019 proposed rule, described in detail in the background documents for that document, as well as additional analyses conducted in response to comments received on that document, the Agency is finalizing the decision that the degree and duration of risk posed by the petroleum and coal products manufacturing industry does not warrant financial responsibility requirements under CERCLA Section 108(b). As such, this rulemaking will not impose CERCLA Section 108(b) financial responsibility requirements for facilities in the petroleum and coal products manufacturing industry. EPA did not receive evidence from any commenter that changed the Agency's determination from that proposed previously.

Central to this final rulemaking decision is EPA's position that the analyses conducted for the proposal are consistent with the statutory language of CERCLA Section 108(b), described in Section IV above (*Statutory Interpretation*). EPA is further assured of this position following the decision by the D.C. Circuit that upheld EPA's interpretation of the statutory language of CERCLA Section 108(b).[73] The analyses consistent with this interpretation showed that under the modern regulatory framework that applies to the petroleum and coal products manufacturing industry, little evidence of burden to the Fund by facilities in this industry exists.

EPA believes that the evaluation of the petroleum and coal products manufacturing industry conclusively demonstrates, by the low occurrence of cleanup sites that significantly impact the Fund, low risk of a Fund-financed response action at current petroleum and coal products manufacturing operations. The reduction in risks, relative to when CERCLA was first established, attributable to the requirements of existing federal and state regulatory programs and voluntary practices, combined with reduced costs to the taxpayer—demonstrated by EPA's cleanup case analysis, existing financial responsibility requirements, and enforcement actions—has reduced the need for federally-financed response action at facilities in the petroleum and coal products manufacturing industry.

VII. Chemical Manufacturing Industry

A. Proposed Rule

On February 21, 2020, EPA published a notice of proposed rulemaking (NPRM) on the third of the three additional industries.[74] In that document, the Agency proposed to not impose financial responsibility requirements for the chemical manufacturing industry and described the analyses and results that were used to reach that decision. Due to the COVID–19 pandemic, several commenters requested an extension to the comment period. EPA extended the comment period by two weeks in response to these requests.[75] The Agency received 16 comments on this proposed rulemaking. Comments received on the proposal and the Agency's responses are laid out in the Response to Comments document found in the docket to this final rulemaking.[76]

B. Summary of Key Comments Received and Agency Response

Of the 16 comments received on the February 21, 2020 NPRM, 6 were in support of the Agency's proposal to not impose financial responsibility

docket as PDF titled ''Sunoco PPA Executed 8 17 12.pdf.''

[70] See spreadsheet, in docket for this action, titled ''NAICS 324_Incident research.xlsx''.

[71] US EPA Emergency Operations Center Spot Report: Region 6, ExxonMobil Refinery Fire Baton Rouge, LA, NRC#1271029, February 12, 2020.

[72] See *ExxonMobil Baton Rouge Refinery Fire Response—February 2020 https://corporate.exxonmobil.com/-/media/Global/Files/locations/United-States-operations/Baton-Rouge/021120-Baton-Rouge-Refinery-information.pdf.*

[73] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494 (D.C. Cir. 2019).

[74] 85 FR 10128 (Feb. 21, 2020).

[75] 85 FR 21366 (Apr. 17, 2020).

[76] *Response to Comments Document: Financial Responsibility Requirement Under CERCLA 108(b) for Classes of Facilities in the Chemical Manufacturing Industry, November, 2020.*

requirements for the chemical manufacturing industry and 10 were opposed.

1. Comments in Support of the Proposal

Of the six comments in support of the proposed rule, three were from the fertilizer industry; one comment from three associations (the American Fuel and Petrochemical Manufacturers, the American Chemistry Council, and the Society of Chemical Manufacturers and Affiliates (SOCMA)); one comment from the Superfund Settlements Project; and one multi-industry comment from the U.S. Chamber of Commerce.

Commenters supporting the proposed rule cited the extensive federal and state requirements that are already in place and agreed that no additional requirements under CERCLA Section 108(b) are warranted for the chemical manufacturing industry. Commenters felt the February 21, 2020 proposal was fully consistent with EPA's final determination on the hardrock mining industry, which was upheld by the D.C. Circuit.[77]

In addition, SOCMA, along with its sister associations, submitted a technical report which reviewed EPA's analysis. The report's conclusions validate EPA's findings, and concluded that ''taxpayer-funded cleanups at chemical manufacturing facilities are even less likely than EPA estimated.'' [78]

2. Comments Opposed to the Proposal

Six comments received were from private citizens opposed to the proposed rule. Most private citizen commenters opposed to the proposal stated a general belief that companies should be liable for their pollution, not taxpayers. It should be noted that the Agency's decision to not impose financial responsibility requirements under Section 108(b) does not diminish liability under CERCLA, and the cost of cleanups will continue to be the responsibility of the PRPs, not the Fund. The Agency also received comments from the Confederated Tribes of the Grand Ronde Community of Oregon, the Little Traverse Bay Bands of Odawa Indians, and Earthjustice. Earthjustice submitted comments on behalf of Communities for a Better Environment, Center for International Environmental Law, Public Citizen, Earthworks, Sierra Club, Idaho Conservation League, Center for Biological Diversity, Ohio Valley Environmental Coalition, and Great Basin Resource Watch.

Many of the comments received on the chemical manufacturing industry proposal were critical of the Agency's interpretation of the statute and the analyses EPA conducted to conclude that no CERCLA Section 108(b) financial responsibility rules are necessary. The statutory interpretation presented in the CERCLA Section 108(b) Hardrock Mining Final Rule (described in *Statutory Interpretation* section above) continues to be the view of the Agency, and that interpretation is not reopened here. After consideration of the critical comments, EPA still concludes that the analyses conducted and information considered were appropriate, consistent with CERCLA, and show that risk posed by the chemical manufacturing industry does not warrant financial responsibility requirements under CERCLA Section 108(b).

As part of the chemical manufacturing industry proposal, EPA systematically evaluated CERCLA NPL, Superfund Alternative Approach (SAA), and removal sites in the industry where releases and cleanup actions occurred. Specifically, EPA developed an analytic approach that considered cleanup cases to identify instances of releases at currently operating facilities where taxpayer funds were expended for response action. See discussion in the proposed rule [79] for a detailed description of the analysis conducted. EPA's review of the Superfund NPL, SAA, and removal sites associated with the industry found that 34 sites indicated a potential for a significant impact to the Fund while operating under the modern regulatory framework. This is a relatively small number of cases in comparison to the approximately 13,480 establishments currently operating in the industry. As noted above, EPA's additional research into facilities referenced by a commenter in opposition to the proposal did not identify any additional Superfund sites in the industry that had burdened the Fund. EPA believes that the small set of federally funded cleanup cases due to recent contamination, in view of the size of the industry, does not warrant the imposition of costly financial responsibility requirements on the entire chemical manufacturing industry under CERCLA Section 108(b).

Additionally, as part of its proposal, to understand the modern regulatory framework applicable to currently operating facilities within the chemical manufacturing industry, EPA compiled applicable federal and state regulations.[80] Specifically, EPA looked to regulations that address the types of releases identified in the cleanup cases. This review also considered industry voluntary programs that could reduce risk of releases. Finally, EPA also identified financial responsibility regulations that apply to facilities in the chemical manufacturing industry, [81] and compliance and enforcement history for the relevant regulations.[82] Regarding concerns expressed in the comments, EPA notes that RCRA corrective action is an example of a control that could apply broadly in the chemical manufacturing industry to facilities that operate as permitted or interim status RCRA treatment, storage, and disposal (TSD) facilities. Both current and former chemical manufacturing facilities are included in the universe of RCRA corrective action facilities. The corrective action program achieves risk reduction through two avenues, by providing a mechanism to clean up contamination as well as authority to require financial assurance. Pursuant to RCRA, as amended by HSWA (Hazardous and Solid Waste Amendments), statutory and regulatory requirements, EPA requires owners and operators of facilities that treat, store or dispose of hazardous waste to investigate and clean up releases of hazardous waste and hazardous constituents from any solid waste management units, thus reducing the likelihood that these facilities would require cleanup under Superfund. RCRA permits issued to TSD facilities must include provisions for both corrective action and financial assurance to cover the costs of implementing those cleanup measures. EPA also possesses additional authorities to order corrective action through enforcement orders, which are not contingent upon a facility's permit. EPA asserts that these features reduce the likelihood of burden to the Fund. Based on this review, and after reviewing the comments received, EPA maintains its preliminary conclusion that the network of federal and state regulations applicable to the chemical manufacturing industry creates a comprehensive framework that applies to prevent releases that could result in

[77] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494 (D.C. Cir. 2019).

[78] EPA–HQ–OLEM–2019–0086–1036.

[79] 85 FR 10128, 10135–10144 (Feb. 21, 2020).

[80] *Summary Report: Federal and State Environmental Regulations and Industry Voluntary Programs in Place to Address CERCLA Hazardous Substances at Chemical Manufacturing Facilities.*

[81] *Review of Existing Financial Responsibility Laws Potentially Applicable to Classes of Facilities in the Chemical Manufacturing Industry.*

[82] *Enforcement, Court Settlements and Judgments in the Chemical Manufacturing Industry.*

a need for a Fund-financed response action.

As discussed in the February 21, 2020 proposed rule, EPA had developed an analytic approach to determine whether the current risk under a modern regulatory framework within the chemical manufacturing industry rose to a level that warrants imposition of financial responsibility requirements under CERCLA Section 108(b).[83] Earthjustice commented that relying on the term ''modern'' is EPA's ''basis for ignoring releases that occurred at facilities before 1980.'' [84] The Agency uses the term modern in this case to distinguish the current regulatory landscape versus the one that existed at the time of the passage of the CERCLA statute. Acknowledgment of current federal and state laws that specifically address risks posed by this industry is appropriate to consider in determining whether there is risk of future Fund expenditures. In particular, in the proposal, EPA identified the prevalent sources of risk that were identified in the cleanup cases reviewed. EPA then evaluated the extent to which activities that contributed to the risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances are now regulated. EPA recognized that substantial advances had been made in the development of manufacturing, pollution control, and waste management practices, as well as the implementation of federal and state regulatory programs to both prevent and address such releases at facilities in the chemical manufacturing industry. This analysis is consistent with the approach utilized in the Final Action for Facilities in the Hardrock Mining Industry and upheld by the D.C. Circuit.[85]

Earthjustice also raised the point that the existence of federal and state regulations does not ensure prevention of releases, and that legacy contamination exists at currently operating facilities. EPA notes that financial responsibility requirements under Section 108(b) would not apply to legacy operations that are no longer operating. Rather, any Section 108(b) requirements would apply to facilities that follow current industry practices and are subject to the modern regulatory framework (*i.e.,* the regulations currently in place that apply to the industry). These modern conditions include federal and state regulatory requirements and financial responsibility requirements that currently apply to operating facilities. In contrast to Earthjustice's point, EPA's analysis found that the efficacy of current regulations, as well as voluntary industry practices, while difficult to quantify, have had a demonstrably positive effect in reducing the number of cleanups that require taxpayer expenditures. This was borne out in the analyses conducted in the proposed rule, the results of which indicated that there was no need for further financial responsibility requirements on this industry.

Earthjustice disagreed with EPA's screening out from its analyses sites where the response actions were funded by private parties as opposed to the government. Earthjustice suggested that it is contrary to CERCLA to focus only on financial risk. In addition, Earthjustice raised concerns about the magnitude and potential long duration of cleanups in the industry.

As a primary matter, EPA's approach and the factors the Agency considered to determine whether or not financial responsibility requirement were appropriate for the chemical manufacturing industry is consistent with CERCLA (see *Statutory Interpretation* section above). A chief factor of the Agency's determination was the results of EPA's cleanup case analysis which involved a systematic examination of Superfund sites (NPL, removal, and SAA). EPA's analysis, described in detail in section VII of the proposed rule,[86] showed that few facilities operating under modern conditions, in light of the size of the industry, have historically burdened the Fund. Specifically, there are relatively few NPL and removal sites with pollution that occurred under a modern regulatory framework associated with the chemical manufacturing industry that required significant Fund expenditures to address. This is, in part, due to the fact that the potentially responsible parties (PRPs) led approximately half of the cleanups identified. Further supporting this finding is the fact that when a cleanup is required under Superfund or corrective action or RCRA, financial assurance is typically required. Moreover, as discussed below, EPA conducted additional research into examples of releases at facilities in the chemical manufacturing industry identified by commenters. That additional research identified only one new example of the Superfund program bearing the costs of a cleanup associated with releases occurring under a modern regulatory framework. The limited number of actions within the sector, combined with its track record of funding cleanups weighs against the need for regulation under CERCLA Section 108(b).

This comment also intended to suggest that CERCLA Section 108(b) financial responsibility could promote rapid cleanup in instances of pollution. As a primary matter, this is not necessarily the case. EPA believes any CERCLA Section 108(b) financial responsibility required for any industry would complement existing Superfund processes by offering a financial backstop for CERCLA costs and damages (see the relevant language at 84 FR 3400 included in the hardrock mining proposal). The financial responsibility would not modify the existing Superfund enforcement authorities, including those to gather information, identify responsible parties, effect cleanup (especially through EPA's enforcement first policy), assess penalties, or provide for citizen suits. In instances where releases occurred that required a Superfund cleanup, the same Superfund process would occur as does today.

Of note is that the Superfund program protects human health and the environment regardless of whether or not financial responsibility is in place. EPA can invoke its enforcement authorities to protect human health and the environment. For example, EPA can issue a Unilateral Administrative Order or conduct a removal action to mitigate potential risks posed by the site conditions. If the Agency has to use fund resources to conduct a cleanup, EPA can take an enforcement action to recover its CERCLA costs and replenish government resources. It is thus not accurate to suggest a lack of CERCLA Section 108(b) financial responsibility would result in delays of cleanup and therefore an increased risk to human health and the environment.

Earthjustice took issue with EPA's interpretation of the statute, stating that EPA's ''interpretation of the statute to focus solely on the risk of a taxpayer bailout of insolvent companies is contrary to law, because this is not the purpose of CERCLA.'' [87] Earthjustice contends that EPA ignored significant risks to human health and the environment. Earthjustice commented on the long and well-established history of contamination of the Nation's soil and water due to the chemical manufacturing industry, and cited examples of recent cleanups. Nevertheless, EPA believes that the site

[83] 84 FR 36540 (Jul. 29, 2019).

[84] EPA–HQ–OLEM–2019–0086–1036.

[85] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494, (D.C. Cir. 2019).

[86] 85 FR 10128, 10135 (Feb. 21, 2020).

[87] Id.

analysis for this rulemaking effectively considered human health and environmental risk in multiple steps. First, EPA examined through the Agency's industry practices and environmental characterization analysis the operational practices and environmental profile of the chemical manufacturing industry. This analysis included an examination of the potentially hazardous materials used in the industry, hazardous wastes generated by industry processes, the units used to manage wastes at these sites, how on-site management of these materials can potentially contribute to releases, and what contaminants might be released by the industry that could impact human health and the environment. Next, EPA investigated in what ways the industry is subject to a wide range of modern federal and state regulatory requirements and enforcement oversight imposed to address this potential human health and environment risk. In these analyses, EPA outlined the framework of modern federal and state regulatory programs to which the industry is subject [88] and also examined compliance and enforcement for the industry,[89] which collectively demonstrate how these components work to address potential risk for modern industry operations. Overall, EPA's full analytic approach developed for the proposed rule examined sites with a variety of contaminants and contaminated media. In effect, the analysis considered the types of human health and environmental risk the Superfund program was designed to address, and that would be addressed by any CERCLA Section 108(b) financial responsibility. This analysis employed by the Agency is consistent with EPA's interpretation of the statutory language and was upheld by the D.C. Circuit,[90] which found that EPA's focus on risk of taxpayer-funded response actions was reasonable. Specifically, the Court stated in its decision, ''we defer to the EPA's interpretation that it should set financial responsibility regulations based on financial risks, not risks to health and the environment.'' EPA's analysis based on this interpretation showed that there is little evidence of the facilities operating under a modern regulatory framework burdening the Fund.

Commenters asserted that, too often, companies file for bankruptcy and avoid financial responsibility for cleaning up harmful pollution. To further assess these concerns, EPA updated its analysis supporting the Economic Sector Profile originally conducted in support of the proposed rulemaking. These analyses rely on industry-wide ratio measures of economic stability that are widely used as standard market metrics for such industry by industry comparisons. This update was conducted with the most recent prior year's worth of data available at the close of comment period for the proposed rule. This updated analysis finds the financial stability of the industry relatively unchanged from the original report, further suggesting that the economic conditions of the industry as a whole are not at undue risk.[91] Added factors such as increased transparency from the application of generally accepted accounting practices, and added levels of bankruptcy protection against defaults on environmental liabilities, while not a guarantee, can reduce potential risks to the Fund even further.

EPA disagrees with Earthjustice's comment suggesting that enforcement activities are halted when there are disruptions caused by unforeseen circumstances, or that enforcement in general is a weakness of the modern regulatory framework structure. The commenter specifically referenced a global pandemic, presumably implying that the coronavirus (COVID–19) pandemic has halted enforcement at the federal and state level. While EPA made certain adjustments that were necessary to maintain public safety, EPA disagrees with the commenter's implicit claim that enforcement has halted, or that the level of enforcement undercuts existing environmental protections or EPA's analysis that considered the existing regulations in evaluating the need for CERCLA Section 108(b) financial responsibility.

In fact, EPA's enforcement program remained very active during the public health emergency. For example, from March 16–August 31, 2020, EPA opened 128 criminal enforcement cases, charged 36 defendants, initiated 603 civil enforcement actions, concluded 629 civil enforcement actions, secured $80.4 million in Superfund response commitments, and obtained commitments from parties to clean up 1,032,832 cubic yards of contaminated soil and water. The COVID–19 pandemic has not meaningfully reduced the protectiveness of existing environmental laws and regulations.

Commenters also questioned the performance of the modern regulatory framework under the potential increased risk of release posed by climate change, seismic hazards and other natural disasters. While most accidents and releases do not lead to Superfund responses, Fund expenditures, or CERCLA liability claims, and the commenters provided no indication a Superfund response resulted from a natural disaster, EPA's analysis has shown that existing regulations in the modern regulatory framework address these concerns.

Several environmental laws authorize regulations requiring the development of response plans for a variety of emergencies, including various natural disasters, in order to reduce the effects of a release, and to notify local emergency response personnel and facilitate cooperation. For example, under 40 CFR part 264, subpart B, facility standards for owner and operators of hazardous waste treatment, storage and disposal facilities must meet location standards, including consideration of seismic environment, floodplains, and salt dome formations. Under 40 CFR part 264, subpart D, owners and operators of hazardous waste facilities must have a contingency plan designed to minimize hazards to human health or the environment from fires, explosions, or the release of hazardous waste or hazardous waste constituents. The contingency plans establish the actions personnel must take in response to fires, explosions, or the release of hazardous waste or hazardous waste constituents. Owners and operators may fulfill the requirements of this subpart by amending existing emergency contingency plans, including Spill Prevention, Control and Countermeasure plans.

In 1989, OSHA promulgated the Hazardous Waste Operations and Emergency Response standards (HAZWOPER). HAZWOPER addresses the health and safety risks to workers of unexpected releases or the threat of releases of hazardous substances that may accompany operational failures, natural disasters, or waste dumped in the environment. OSHA promulgated the standards to ensure the safe and effective management and cleanup of unexpected releases of hazardous substances. The regulations require employers to develop a written program for their employees to address hazards and provide for emergency response actions, including an organizational

[88] *Summary Report: Federal and State Environmental Regulations and Industry Voluntary Programs in Place to Address CERCLA Hazardous Substances at Chemical Manufacturing Facilities.*

[89] *Enforcement, Court Settlements and Judgments in the Chemical Manufacturing Industry.*

[90] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494 (D.C. Cir. 2019).

[91] *Addendum Update to CERCLA 108(b) Economic Sector Profile: NAICS 325—Chemicals Manufacturing; May 2020.*

structure, comprehensive work plan, training programs, and medical surveillance program. In 2002, OSHA expanded its emergency response regulations through the implementation of Emergency Action Plans (EAPs). The regulations require that employers prepare a written EAP to create practices to follow during workplace emergencies at a given facility.

In addition, EPA implements the Chemical Accident Prevention Provisions of Section 112(r) of the Clean Air Act Amendments, which require certain facilities to generate Risk Management Plans to mitigate the effects of a chemical accident and to coordinate with local response personnel. EPA implements regulations under EPCRA that impose emergency planning, reporting, and notification requirements for hazardous and toxic chemicals.

EPA appreciated the comments offering examples of sites of concern and undertook additional due diligence to examine some of these releases and accidents referenced by the commenter. While most accidents and releases do not lead to Superfund responses, Fund expenditures, or CERCLA liability claims, EPA acknowledged that it is possible some of the releases and accidents may have required Superfund actions, which the Agency may have missed in the analysis conducted as part of the proposal. As such, EPA examined a selection of the cases referenced by Earthjustice to better understand the consequences of these incidents, to the extent possible. In the case of the chemicals manufacturing industry, most of the facilities referenced by the commenters were referenced by facility name. With the exception of two facilities already included in the Agency's analysis of NPL cleanup sites, EPA conducted additional research into all of the facilities referenced.

The examination of these facilities did not identify any new instances of a facility in the chemicals manufacturing industry burdening the Superfund, and only one example of a previously unidentified CERCLA action. In that one case, a CERCLA enforcement action related to the DuPont (now Chemours) plant in Belle, WV, DuPont paid a penalty and agreed to corrective actions designed to reduce the likelihood of release going forward. Notably, many of the incidents were addressed by existing state or federal authorities.

EPA also examined a couple of geographical areas where the commenter alleged cumulative risks from many chemical manufacturing facilities presents some additional and unique risk. EPA conducted research into the Houston Ship Channel and an 85-mile stretch along the banks of the Mississippi River in Louisiana, nicknamed ''Cancer Alley'', to identify instances of releases and responses in those areas associated with chemical manufacturing facilities. EPA identified 18 facilities in those geographical areas that appeared to have releases or responses worthy of investigation. However, many of the facilities had already been considered in the cleanup case analyses done in support of the proposal. Additionally, many either did not require CERCLA involvement or were addressed and/or funded by the PRP. In total, EPA only identified one additional site in those two areas with pollution that appeared to occur under a modern regulatory framework and where the Fund appeared to have been burdened. This site, the Cusol Company, Inc. site in Houston, TX, required an EPA removal action after the facility was abandoned in 2005. However, the cleanup activities were relatively minor at the site with the removal assessment work conducted within three months and the cleanup itself completed within a month. The identification of one additional site alone does not change EPA's conclusion from the proposal that CERCLA Section 108(b) financial responsibility is not necessary for the industry. More information on the incidents cited by commenters and researched by EPA is provided in the spreadsheet titled *NAICS 325 Incident research* containing the information gathered, information sources considered and summary findings.[92]

In addition to completing examination of the incidents cited in comments, EPA is also aware of some recent incidents of releases from chemical manufacturing facilities, for example, the Alchemix Chemical Fire in College Park, GA and Poly-America Fire in Grand Prairie, TX. Both examples exhibit coordinated response of local and federal services that demonstrate the expected performance of the modern regulatory framework. In the Alchemix Chemical Fire that occurred on July 17, 2020, the Fulton County Emergency Management Director and Georgia Environmental Protection Division (GAEPD) requested EPA's assistance with air monitoring and response efforts. EPA mobilized an On-Scene Coordinator (OSC) and Superfund Technical Assessment & Response Team (START) resources in response to the fire. The OSC arrived on site and worked with the fire chief, GAEPD and a representative of the responsible party. After the fire was extinguished by the local fire department and the responsible party hired an environmental contractor, EPA demobilized, and oversight of environmental clean-up was conducted by GAEPD under its state authorities.[93]

The Poly-America Fire that occurred on August 18, 2020, was responded to by local fire departments as part of an Incident Management Team under unified command with the City of Grand Prairie and the Texas Commission on Environmental Quality (TCEQ). In addition, EPA lent specialized expertise in deploying support from EPA Consequence Management Advisory Division and START contractors to assist in air monitoring in the local area. EPA resources were demobilized after no detections at or near screening levels were found.[94]

Although these incidents were not cited by commenters, and though releases to air as occurred in these examples have not been identified as prevalent causes of inclusion of a site on the NPL, EPA offers that the prompt responses that took place following these incidents illustrate the protective function of the modern regulatory framework. Coordinated responses at chemical manufacturing facilities when incidents do occur lessen the likelihood of these facilities becoming Superfund sites, which further weighs against the need for financial responsibility requirements for the chemical manufacturing industry under CERCLA Section 108(b). Furthermore, these example responses demonstrate that authorities already in place to respond to incidents provide state and local entities the tools to take actions that address many of the risks that might result in a Superfund site.

C. Decision To Not Impose Requirements

Based on the analyses conducted for the February 21, 2020 proposed rule, described in detail in the background documents for that document, as well as additional analyses conducted in response to comments received on that document, the Agency is finalizing the decision that the degree and duration of risk posed by the chemical manufacturing industry does not warrant financial responsibility requirements under CERCLA Section

[92] See spreadsheet, in docket for this action, titled ''NAICS 325_Incident research.xlsx''.

[93] US EPA. Emergency Operations Center Spot Report: Region 4, Alchemix Chemical Fire, College Park, GA, NRC#1282206, July 18, 2020.

[94] US EPA. Emergency Operations Center Spot Report: Region 6, Poly-America Fire, Grand Prairie, TX, NRC#1284921, August 19, 2020.

108(b). As such, this rulemaking will not impose CERCLA Section 108(b) financial responsibility requirements for facilities in the chemical manufacturing industry. EPA did not receive evidence from any commenter that changed the Agency's determination from that proposed previously.

Central to this final rulemaking decision is EPA's position that the analyses conducted for the proposal are consistent with the statutory language of CERCLA Section 108(b), described in Section IV above (*Statutory Interpretation*). EPA is further assured of this position following the decision by the D.C. Circuit that upheld EPA's interpretation of the statutory language of CERCLA Section 108(b).[95] The analyses consistent with this interpretation showed that under the modern regulatory framework that applies to the chemical manufacturing industry, little evidence of burden to the Fund by facilities in this industry exists.

EPA believes that the evaluation of the chemical manufacturing industry conclusively demonstrates, by the low occurrence of cleanup sites that significantly impact the Fund, low risk of a Fund-financed response action at current chemical manufacturing operations. The reduction in risks, relative to when CERCLA was first established, attributable to the requirements of existing federal and state regulatory programs and voluntary practices combined with reduced costs to the taxpayer—demonstrated by EPA's cleanup case analysis, existing financial responsibility requirements, and enforcement actions—has reduced the need for federally-financed response action at facilities in the chemical manufacturing industry.

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

These actions are significant regulatory actions that were submitted to the Office of Management and Budget (OMB) for review, because they may raise novel legal or policy issues [3(f)(4)]. Any changes made in response to OMB recommendations have been documented in the docket. EPA did not prepare an economic analysis for these final rulemakings because no regulatory provisions are being finalized.

[95] *Idaho Conservation League* v. *Wheeler,* 930 F.3d 494 (D.C. Cir. 2019).

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This final rule is not subject to the requirements of E.O. 13771 (82 FR 9339, February 3, 2017) because this final rule does not alter any regulatory requirements.

C. Paperwork Reduction Act (PRA)

These actions do not impose an information collection burden under the PRA, because they do not impose any regulatory requirements.

D. Regulatory Flexibility Act (RFA)

I certify that these actions will not have a significant economic impact on a substantial number of small entities under the RFA. These actions will not impose any requirements on small entities.

E. Unfunded Mandates Reform Act (UMRA)

These actions do not contain any unfunded mandates as described in UMRA, 2 U.S.C. 1531–1538, and do not significantly or uniquely affect small governments, because they do not impose any regulatory requirements.

F. Executive Order 13132: Federalism

These actions do not have federalism implications. They will not have substantial direct effects on the states, on the relationship between the Federal Government and the states, or on the distribution of power and responsibilities among the various levels of government, since they impose no regulatory requirements.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

These actions do not have tribal implications as specified in Executive Order 13175, because they impose no regulatory requirements. Thus, Executive Order 13175 does not apply to these actions. However, EPA offered consultation and coordination with federally recognized tribes as well as with Alaska Native Claims Settlement Act Corporations during the rulemaking process. EPA sent notification letters to all 574 federally recognized tribes and to the 12 Alaska Native Claims Settlement Act Regional Corporation Executive Directors for each of the three separate proposals. EPA also held public informational webinars for each of the proposed rules and tribes participated in all three webinars. EPA received one comment from a tribe on the Electric Power Generation, Transmission and Distribution industry proposal and two comments on the Chemical Manufacturing industry proposal. All three comments opposed the proposal to not impose financial responsibility requirements. These comments and EPA's responses are included in the Response to Comments documents, which are part of the dockets for these final actions.[96] For more information on the consultation and coordination for these rules, see the consultation summaries in the docket.

H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

These actions are not subject to Executive Order 13045 because they are not economically significant as defined in Executive Order 12866 and they do not establish any new environmental health or safety standard.

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

These actions are not a ''significant energy action'' because they are not likely to have a significant adverse effect on the supply, distribution, or use of energy, since they impose no regulatory requirements; in addition, these actions have not otherwise been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

J. National Technology Transfer and Advancement Act

These rulemakings do not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes that these actions are not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because these actions establish that no federal CERCLA Section 108(b) financial responsibility requirements are necessary and do not establish any new environmental health or safety standard. Thus, no review of these final actions under Executive Order 12898 is necessary.

[96] *Response to Comments Document: Financial Responsibility Requirement Under CERCLA 108(b) for Classes of Facilities in the Electric Power Generation, Transmission, and Generation Industry, November, 2020.; Response to Comments Document: Financial Responsibility Requirement Under CERCLA 108(b) for Classes of Facilities in the Petroleum and Coal Products Manufacturing Industry, November, 2020.; Response to Comments Document: Financial Responsibility Requirement Under CERCLA 108(b) for Classes of Facilities in the Chemical Manufacturing Industry, November, 2020.*

L. Congressional Review Act (CRA)

This action is subject to the CRA, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 320

Environmental protection, Financial responsibility, Hazardous substances.

Andrew Wheeler,

Administrator.

[FR Doc. 2020–26379 Filed 12–1–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS–5527–CN]

RIN 0938–AT89

Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects technical and typographical errors that appeared in the final rule published in the September 29, 2020 **Federal Register** entitled ''Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures,'' which established the Radiation Oncology Model and the End-Stage Renal Disease Treatment Choices Model.

DATES: Effective date: This correcting document is effective on December 2, 2020.

FOR FURTHER INFORMATION CONTACT: Rebecca Cole, (410) 786–1589.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2020–20907 of September 29, 2020 (85 FR 61114), there were a number of technical errors that are identified and corrected in this correcting document. The provisions in this correction document are effective as if they had been included in the document published September 29, 2020. Accordingly, the corrections are effective November 30, 2020.

II. Summary of Errors

On page 61159, in our discussion of the entitled ''Episode Length'' there is an error in an in-text citation to the proposed rule, so 84 FR 3499 is corrected to 84 FR 34499, along with the correct link to the proposed rule.

On pages 61289, 61292, 61295, 61296, 61297, 61319, 61327, 61328, 61329, 61349, 61350, 61353, and 61354, we made errors in the numbering and reference numbers for several tables.

On pages 61357, 61358, and 61359 in our discussion of the effects on Radiation Oncology (RO) Participants, we made errors in wage-related information. On page 61359, in our discussion of the Regulatory Flexibility Act requirements for the Radiation Oncology Model, we made a calculation error regarding the distribution of payment changes. Under Medicare FFS, physician group practices (PGPs) are largely paid through the Medicare Physician Fee Schedule (PFS) for radiotherapy services while hospital outpatient departments (HOPDs) are paid through the Outpatient Prospective Payment System (OPPS). Unit-cost increases under the PFS are projected to be lower than under the OPPS. Therefore, the RO Model will affect payments to RO participants that are PGPs and HOPDs differentially over time through the use of a site neutral update factor. The referenced calculations are revised to properly value this effect.

III. Waiver of Proposed Rulemaking, 60-Day Comment Period, and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of the proposed rulemaking in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA (5 U.S.C. 553(d)) and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in the effective date APA requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment rulemaking processes are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and the agency includes a statement of support.

We believe that this correcting document does not constitute a rule that would be subject to the notice and comment or delayed effective date requirements. This document corrects technical and typographic errors in the Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures final rule (the Specialty Care Models final rule), but does not make substantive changes to the policies or payment methodologies that were adopted in the final rule. As a result, this corrective document is intended to ensure that the information in the Specialty Care Models final rule accurately reflects the policies adopted in that document.

In addition, even if this was a rulemaking to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the final rule would be contrary to the public interest because it is in the public's interest for model participants to receive appropriate payments in as timely a manner as possible and to ensure that the Specialty Care Models final rule accurately reflects our methodologies and policies as of the date they take effect and are applicable.

Furthermore, such procedures would be unnecessary, as we are not altering the implementation of the models or the way participants in the models will perform, but rather we are simply correctly implementing the policies that we previously proposed, received comment on, and subsequently finalized. This correcting document is intended solely to ensure that the Specialty Care Models final rule accurately reflects these payment methodologies and policies. For these reasons, we believe we have good cause to waive the notice and comment and effective date requirements.

IV. Correction of Errors

In FR Doc. 2020–20907 of September 29, 2020 (85 FR 61114), make the following corrections:

1. On page 61159, first column, last paragraph, lines 1 and 2, the reference ''(84 FR 3499)'' is corrected to read ''(84 FR 34499)''.

2. On page 61289, lower one-fourth of the page, the table title ''TABLE 11: PROPOSED HDPA SCHEDULE'' is corrected to read ''TABLE 15: PROPOSED HDPA SCHEDULE''.

3. On page 61292, in the middle of the page, the table title ''TABLE 11.a: HDPA SCHEDULE'' is corrected to read ''TABLE 15.a: HDPA SCHEDULE''.

4. On page 61295, third column, last partial paragraph, line 1, the reference ''Table 12'' is corrected to read ''Table 16''.

5. On page 61296—

a. Top of the page, the table title ''TABLE 12: PROPOSED ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS'' is corrected to read ''TABLE 16: PROPOSED ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS''.

b. Lower half of the page, second column, partial paragraph, line 2, the table reference ''Table 12.a'' is corrected to read ''Table 16.a''.

6. On page 61297, the table title, ''TABLE 12.a: ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS'' is corrected to read ''TABLE 16.a: ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS''.

7. On page 61319, the table title, ''TABLE 13: PROPOSED SCORING METHODOLOGY FOR ASSESSMENT OF MEASUREMENT YEARS 1 AND 2 ACHIEVEMENT SCORES AND IMPROVEMENT SCORES ON THE HOME DIALYSIS RATE AND TRANSPLANT RATE'' is corrected to read ''TABLE 17: PROPOSED SCORING METHODOLOGY FOR ASSESSMENT OF MEASUREMENT YEARS 1 AND 2 ACHIEVEMENT SCORES AND IMPROVEMENT SCORES ON THE HOME DIALYSIS RATE AND TRANSPLANT RATE''.

8. On page 61327, the table title, ''TABLE 14: PROPOSED FACILITY PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE'' is corrected to read ''TABLE 18: PROPOSED FACILITY PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE''.

9. On page 61328—

a. Top of the page, first column, first full paragraph, line 8, the phrase ''Table 14.a'' should read ''Table 18.a''.

b. Middle of the page, the table title ''TABLE 14a: FACILITY PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE'' is corrected to read ''TABLE 18.a: FACILITY PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE''.

c. In the third column, first full paragraph, line 1, the table reference, ''Table 15'' is corrected to read ''Table 19''.

10. On page 61329—

a. Top of the page, the table title, ''TABLE 15: PROPOSED CLINICIAN PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE'' is corrected to read ''TABLE 19: PROPOSED CLINICIAN PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE''

b. Top half of page (after Table 15), second column, partial paragraph, line 5, the table reference ''Table 15.a'' is corrected to read ''Table 19.a''.

c. Lower half of the page, the table title, ''TABLE 15a: CLINICIAN PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE'' is corrected to read ''TABLE 19.a: CLINICIAN PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE''.

11. On page 61349, first column, first full paragraph, last line, the table reference ''Table 2'' is corrected to read ''Table 21''.

12. On page 61350—

a. First column, last full paragraph, line 1, the table reference ''Table 1'' is corrected to read ''Table 20''.

b. Second column; first paragraph, line 35, the table reference ''Table 1'' is corrected to read ''Table 20''.

13. On page 61351, top of the page, the table title, ''TABLE 1. ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS $) FOR RADIATION ONCOLOGY MODEL (Starting January 1, 2021)'' is corrected to read ''TABLE 20: ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS $) FOR RADIATION ONCOLOGY MODEL (Starting January 1, 2021)''

14. On page 61353, first column, first paragraph—,

a. Line 1, the table reference ''Table 2'' is corrected to read ''Table 21''.

b. Line 16, the table reference ''Table 2'' is corrected to read ''Table 21''.

15. On page 61354—

a. Top of the page, the table title, ''TABLE 2. ESTIMATES OF MEDICARE PROGRAM SAVINGS (ROUNDED $M) FOR ESRD TREATMENT CHOICES MODEL'' is corrected to read ''TABLE 21: ESTIMATES OF MEDICARE PROGRAM SAVINGS (ROUNDED $M) FOR ESRD TREATMENT CHOICES MODEL''.

b. Lower half of the page, first column, last paragraph, line 4, the table reference ''Table 2'' is corrected to read ''Table 21''.

16. On page 61355, first column, first full paragraph—

a. Line 9, the table reference, ''Table 2'' is corrected to read ''Table 21''.

b. Line 21, the table reference, ''Table 2'' is corrected to read ''Table 21''.

17. On page 61357, third column—

a. Last paragraph, line 19, the figure ''$19.40'' is corrected to read ''$20.50''

b. Last paragraph, line 21, the figure ''$38.80'' is corrected to read ''$41.00''

c. Last footnote (footnote 175), line 2, the figure ''$19.40'' is corrected to read ''$20.50''.

18. On page 61358—

a. First column, in the first partial paragraph,

(1) Line 2, the figure ''$183.14'' should be replaced with ''$193.52''

(2) Line 4, the figure ''$173,983'' should be replaced with ''$183,844.00'',

(3) Line 5, the figure ''$183.14'' should be replaced with ''$193.52''

(4) Line 6, the figure ''$173,983'' should be replaced with ''$183,844.00''.

b. First column, fourth full paragraph—

(1) Line 12, the figure ''$1,743.07'' is corrected to read ''$1,845.00''.

(2) Line 18, the figure ''$1,655,916.50'' is corrected to read ''$1,752,750.00''.

c. Second column, first full paragraph—

(1) Line 11, the figure ''$1,093.26'' is corrected to read ''$1,106.94''.

(2) Line 13, the figure ''$3,170,454.00'' is corrected to read ''$3,210,126.00''.

(3) Line 14, the phrase ''$1,093.269/participant'' is corrected to read ''$1,106.94/participant''.

(4) Line 20, the figure ''$3,019.47'' is corrected to read ''$3,145.46'' and ''$1,093.26'' is corrected to read $1,106.94''.

(5) Line 21, the figure ''$183.14'' is corrected to read ''$193.52''.

(6) Line 23, the figure ''$1,743.07'' is corrected to read ''$1,845.00''.

(7) Line 25, the figure ''$2,868,496.50'' is corrected to read ''$2,988,187.00''.

(8) Line 27 the figure ''$2,131,350.00'' is corrected to read ''$2,158,533.00''.

(9) Line 30, the figure ''$4,999,846.50'' is corrected to read ''$5,146,720.50''.

19. On page 61359—

a. First column, first full paragraph—

(1) Line 4, the phrase ''reduced by 6.0'' is corrected to read ''increased by 1.6''.

(2) Line 6 the phrase ''reduced by 4.7'' is corrected to read ''reduced by 8.7''.

(3) Line 22, the figure ''$1,743.06'' is corrected to read ''$1,845.00''.

(3) Line 23 to 26, the sentence ''We assume that our estimate for the

submission of quality measures remains an accurate estimate at $310.40 per year.'' is corrected to read, ''We revise our estimate for the submission of quality measures to an estimated $328.00 per year.''

(5) Line 28, ''$1,432.67'' is corrected to read ''$1,517.00'', and ''$38.80'' is corrected to read ''$41.00''.

c. Second column—

(1) First full paragraph—

(a) Line 6, the figure ''$1,093.26'' is corrected to read ''$1,106.94''.

(b) Line 8, the figure ''$183.14'' is corrected to read ''$193.52''.

(c) Line 16, the figure ''$95.90'' is corrected to read ''$97.10''.

(d) Line 28, the parenthetical expression (''$1,093.26 = ($95.20 * 11.4))'' is corrected to read ''($1,106.94 = ($95.20 * 11.4))''.

(e) Line 31, the figure ''$183.14'' is corrected to read ''$193.52''.

(2) Last footnoted paragraph (footnote 181), line 2, the figure ''$47.95'' is corrected to read ''$48.55''.

20. On page 61361, third column, last paragraph, line 4, the phrase ''Tables E3 and E4'' is corrected to read ''Tables 22 and 23''.

21. On page 61362, top of the page—

a. The table title, ''TABLE 3: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR THE RADIATION ONCOLOGY MODEL'' is corrected to read ''TABLE 22: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR THE RADIATION ONCOLOGY MODEL''.

b. The table title, ''TABLE 4: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR END STAGE RENAL DISEASE (ESRD) TREATMENT CHOICES MODEL'' is corrected to read ''TABLE 23: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR END STAGE RENAL DISEASE (ESRD) TREATMENT CHOICES MODEL''

Wilma M. Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2020–26512 Filed 11–30–20; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[RTID 0648–XA683]

Pacific Island Fisheries; 2020 U.S. Territorial Longline Bigeye Tuna Catch Limits for the Commonwealth of the Northern Mariana Islands; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Announcement of a valid specified fishing agreement; correction.

SUMMARY: NMFS published a document in the **Federal Register** of November 23, 2020, announcing a valid specified fishing agreement that allocates up to 1,000 metric tons (t) of the 2020 bigeye tuna limit for the Commonwealth of the Northern Mariana Islands (CNMI) to U.S. longline fishing vessels. The document incorrectly referred to American Samoa.

DATES: December 2, 2020.

FOR FURTHER INFORMATION CONTACT: Lynn Rassel, NMFS PIRO Sustainable Fisheries, 808–725–5184.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of November 23, 2020, in FR Doc. 2020–25806, on page 74615, in the first column, correct the second sentence of the **DATES** caption to read: The start date for attributing 2020 bigeye tuna catch to the CNMI was November 15, 2020.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 24, 2020.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–26363 Filed 12–1–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 200221–0062]

RTID 0648–XA647

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is reallocating the projected unused amounts of Pacific cod total allowable catch (TAC) from catcher/processors using hook-and-line gear, catcher vessels less than 50 feet using hook-and-line gear, catcher vessels greater than or equal to 50 feet using hook-and-line gear, and vessels using pot gear to catcher vessels using trawl gear and catcher/processors using trawl gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to allow the 2020 TAC of Pacific cod in the Central Regulatory Area of the GOA to be harvested.

DATES: Effective December 2, 2020 through 2,400 hours, Alaska local time (A.l.t.), December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2020 Pacific cod TAC specified for catcher/processors using hook-and-line gear in the Central Regulatory Area of the GOA is 192 metric tons (mt) as established by the final 2020 and 2021 harvest specifications for groundfish of the GOA (85 FR 13802, March 10, 2020).

The 2020 Pacific cod TAC specified for catcher vessels less than 50 feet using hook-and-line gear in the Central Regulatory Area of the GOA is 550 mt as established by the final 2020 and 2021 harvest specifications for

groundfish of the GOA (85 FR 13802, March 10, 2020).

The 2020 Pacific cod TAC specified for catcher vessels greater than or equal to 50 feet using hook-and-line gear in the Central Regulatory Area of the GOA is 253 mt as established by the final 2020 and 2021 harvest specifications for groundfish of the GOA (85 FR 13802, March 10, 2020).

The 2020 Pacific cod TAC specified for vessels using pot gear in the Central Regulatory Area of the GOA is 1,048 mt as established by the final 2020 and 2021 harvest specifications for groundfish of the GOA (85 FR 13802, March 10, 2020).

The 2020 Pacific cod TAC specified for catcher/processors using trawl gear in the Central Regulatory Area of the GOA is 158 mt as established by the final 2020 and 2021 harvest specifications for groundfish of the GOA (85 FR 13802, March 10, 2020).

The 2020 Pacific cod TAC apportioned to catcher vessels using trawl gear in the Central Regulatory Area of the GOA is 1,567 mt, as established by the final 2020 and 2021 harvest specifications for groundfish of the GOA (85 FR 13802, March 10, 2020).

The Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that catcher/processors using hook-and-line gear will not be able to use 180 mt, catcher vessels less than 50 feet using hook-and-line gear will not be able to use 460 mt, catcher vessels greater than or equal to 50 feet using hook-and-line gear will not be able to use 100 mt, and vessels using pot gear will not be able to harvest 1,040 mt of the 2020 Pacific cod TAC allocated to those vessels under § 679.20(a)(12)(i)(B)(*1*) to (*3*) and (*6*).

In accordance with § 679.20(a)(12)(ii)(B), the Regional Administrator has also determined that catcher vessels using trawl gear and catcher/processors using trawl gear currently have the capacity to harvest this excess allocation. Therefore, NMFS apportions 1,780 mt of Pacific cod from the catcher/processors using hook-and-line gear, catcher vessels less than 50 feet using hook-and-line gear, catcher vessels greater than or equal to 50 feet using hook-and-line gear, and vessels using pot gear apportionments to catcher vessels using trawl gear and catcher/processors using trawl gear in the Central Regulatory Area of the GOA.

The harvest specifications for Pacific cod in the Central Regulatory Area of the GOA included in the final 2020 and 2021 harvest specifications for groundfish of the GOA (85 FR 13802, March 10, 2020) are revised as follows: 12 mt to catcher/processors using hook-and-line gear, 90 mt to catcher vessels less than 50 feet using hook-and-line gear, 153 mt to catcher vessels greater than or equal to 50 feet using hook-and-line gear, 8 mt to vessels using pot gear, 2,521 mt to catcher vessels using trawl gear, and 838 mt to catcher/processors using trawl gear.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of Pacific cod in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 25, 2020.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 27, 2020.

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–26573 Filed 12–1–20; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 85, No. 232

Wednesday, December 2, 2020

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R6–ES–2019–0054; FF09E21000 FXES11110900000 212]

RIN 1018–BE23

Endangered and Threatened Wildlife and Plants; Threatened Species Status for Pinus albicaulis (Whitebark Pine) With Section 4(d) Rule

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list whitebark pine *(Pinus albicaulis*), a high-elevation tree species found across western North America, as a threatened species under the Endangered Species Act of 1973 (Act), as amended. If we finalize this rule as proposed, it would extend the Act's protections to this species. We also propose a rule issued under section 4(d) of the Act that is necessary and advisable to provide for the conservation of the species. We have determined that designation of critical habitat for the whitebark pine is not prudent at this time.

DATES: We will accept comments received or postmarked on or before February 1, 2021. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by January 19, 2021.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R6–ES–2019–0054, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R6–ES–2019–0054, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see *Public Comments,* below, for more information).

FOR FURTHER INFORMATION CONTACT: Tyler Abbott, Field Supervisor, U.S. Fish and Wildlife Service, Wyoming Ecological Services Field Office, 5353 Yellowstone Road, Suite 308A, Cheyenne, WY 82009; telephone 307–772–2374. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if a species is determined to be an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within 1 year. Critical habitat shall be designated, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designations and revisions of critical habitat can only be completed by issuing a rule. We have determined that designating critical habitat at this time is not prudent for *Pinus albicaulis* (hereafter, whitebark pine), for the reasons discussed below.

This rule proposes the listing of the whitebark pine as a threatened species. The whitebark pine has been a candidate species for listing since 2011. This rule and the associated species status assessment (SSA) report assess all previous and new available information regarding the status of and threats to the whitebark pine. We also propose a rule issued under section 4(d) of the Act that is necessary and advisable to provide for the conservation of the species.

The basis for our action. Under the Act, we can determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the primary stressor driving the status of the whitebark pine is white pine blister rust, a fungal disease caused by the nonnative pathogen *Cronartium ribicola* (Factor C). Whitebark pine is also impacted by the mountain pine beetle (*Dendroctonus ponderosae*) (Factor C), altered fire regimes (Factor E), and the effects of climate change (Factor E).

Peer review. We requested comments from independent specialists on the SSA report upon which this proposed rule is based, to ensure that we based our determination on scientifically sound data, assumptions, and analyses. Their comments have been incorporated into the SSA report as appropriate. Because we will consider all additional comments and information received during the comment period, our final determination may differ from this proposal. The SSA report and other materials relating to this proposal can be found on the Service's Mountain Prairie Region website at *https://www.fws.gov/mountain-prairie/es/whitebarkPine.php* and at *http://www.regulations.gov* under Docket No. FWS–R6–ES–2019–0054. Because this proposed rule is based on the scientific information in the SSA report, which has already been peer reviewed, we are not seeking additional peer review of this proposed rule, in accordance with Service's August 22, 2016, Director's Memo on the Peer Review Process.

Information Requested

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or

information from other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The whitebark pine's biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including requirements for habitat, nutrition, reproduction, and dispersal;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both, as well as planned conservation efforts.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors, including:

(a) Information regarding the distribution, magnitude, and severity of impacts from white pine blister rust;

(b) Mortality, cone production, and regeneration in areas impacted by mountain pine beetle, wildfire, or white pine blister rust; and

(c) The potential effects of climate change on whitebark pine, its habitat, and the aforementioned factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species, and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

(5) Information concerning activities that should be considered under a rule issued in accordance with section 4(d) of the Act (16 U.S.C. 1531 *et seq.*) as a prohibition or exemption within U.S. territory that would contribute to the conservation of the species. In particular, information concerning whether import, export, and activities related to sale in interstate and foreign commerce should be prohibited, or whether any other activities should be considered excepted from the prohibitions in the 4(d) rule.

(6) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act, including information to inform the following factors such that a designation of critical habitat may be determined to be not prudent:

(a) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(b) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(c) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(d) No areas meet the definition of critical habitat.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.'' You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Wyoming Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register** (see **DATES**). Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT.** We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. For the immediate future, we will provide these public hearings using webinars that will be announced on the Service's website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulation at 50 CFR 424.16(c)(3).

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and the Service's August 22, 2016, Director's Memo on the Peer Review Process, we sought the expert opinions of seven appropriate and independent specialists regarding the SSA report on which this proposed rule is based, and received responses from five. The purpose of peer review of the SSA report is to ensure that our listing determination is based on scientifically sound data, assumptions, and analyses. The peer reviewers had expertise in whitebark pine's biology, habitat management, genetics, and stressors. The peer reviewers reviewed the SSA report, which informed our determination. Comments from peer reviewers have been incorporated into our SSA report as appropriate, and will be available along with other public comments in the docket for this proposed rule.

Previous Federal Actions

On February 11, 1991, we received a petition, dated February 5, 1991, from the Great Bear Foundation of Missoula, Montana, to list the whitebark pine under the Act. The petition stated that whitebark pine was rapidly declining due to impacts from mountain pine beetles, white pine blister rust, and fire suppression. After reviewing the petition, we found that the petition did not provide substantial information indicating that listing whitebark pine may be warranted. We published this finding in the **Federal Register** on January 27, 1994 (59 FR 3824).

On December 9, 2008, we received a petition, dated December 8, 2008, from the Natural Resources Defense Council (NRDC) requesting that we list whitebark pine as endangered throughout its range and designate critical habitat under the Act. The petition clearly identified itself as such and included the requisite identification information for the petitioner, as then required by 50 CFR 424.14(a). The petition included supporting information regarding the species' natural history, biology, taxonomy, lifecycle, distribution, and reasons for decline. The NRDC reiterated the threats from the 1991 petition, and included climate change and successional replacement as additional threats to whitebark pine. In a January 13, 2009, letter to NRDC, we responded that we had reviewed the information presented in the petition and determined that issuing an emergency rule temporarily listing the species under section 4(b)(7) of the Act was not warranted. We also stated that we could not address the petition promptly because of staff and budget limitations. We indicated that we would process a 90-day petition finding as quickly as possible.

On December 23, 2009, we received NRDC's December 11, 2009, notice of intent to sue over our failure to respond to the petition to list whitebark pine and designate critical habitat. We responded in a letter dated January 12, 2010, indicating that other preceding listing actions had priority, but that we expected to complete the 90-day finding during Fiscal Year 2010. On February 24, 2010, NRDC filed a complaint alleging a failure to issue a 90-day finding on the petition. We completed a 90-day finding on the petition, which published in the **Federal Register** on July 20, 2010 (75 FR 42033). In that finding, we determined that the petition presented substantial information such that listing whitebark pine may be warranted, and we announced that we would conduct a status review of the species. We opened a 60-day information collection period to allow all interested parties an opportunity to provide information on the status of whitebark pine (75 FR 42033); during that information collection period, we received 20 letters from the public.

On July 19, 2011, we published a 12-month finding in the **Federal Register** (76 FR 42631), following a review of all available scientific and commercial information. In that finding, we found that listing whitebark pine as endangered or threatened was warranted. However, at that time, listing whitebark pine was precluded by higher priority actions to amend the Lists of Endangered and Threatened Wildlife and Plants, and we added whitebark pine to our candidate species list with a listing priority number of 2, indicating threats that were of high magnitude and were considered imminent. On January 15, 2013, Wildwest Institute and Alliance for the Wild Rockies filed a complaint challenging our finding that listing was ''precluded'' for whitebark pine, based on its listing priority number. On April 25, 2014, the District Court for the District of Montana upheld our finding that listing the whitebark pine was warranted but precluded. The plaintiffs appealed this ruling, and on April 28, 2017, the Ninth Circuit Court of Appeals affirmed the district court's summary judgement in favor of the Service.

Whitebark pine has remained a candidate for listing under the Act since 2011, and we have reevaluated its status on an annual basis through the candidate notice of review (see 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; 80 FR 80584, December 24, 2015; 81 FR 87246, December 2, 2016). The species currently has a listing priority number of 8, indicating threats that are of moderate magnitude and are imminent.

Species Status Assessment

The Service prepared an SSA report for whitebark pine (Service 2018). The science provided in the SSA report is the basis for this proposed rule. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species. The SSA report underwent independent peer review by scientists with expertise in whitebark pine's biology, habitat management, genetics, and stressors (factors negatively affecting the species). The SSA report and other materials relating to this proposal can be found on the Service's Mountain Prairie Region website at *https://www.fws.gov/mountain-prairie/es/whitebarkPine.php* and at *http://www.regulations.gov* under Docket No. FWS–R6–ES–2019–0054.

I. Proposed Threatened Species Status for the Whitebark Pine

Background

A thorough review of the distribution, taxonomy, life history, and ecology of the whitebark pine is presented in the SSA report (Service 2018, chapter 2), which is available at *https://www.fws.gov/mountain-prairie/es/whitebarkPine.php* and at *http://www.regulations.gov* under Docket No. FWS–R6–ES–2019–0054. A brief summary appears below.

Whitebark pine is a slow-growing, long-lived tree, occurring at high elevations across the western United States and Canada. The species is a five-needle conifer placed in the subgenus *Strobus,* which includes other five-needle white pines. No taxonomic subspecies or varieties of whitebark pine are recognized (COSEWIC 2010, p. 6). Based on this taxonomic classification information, we recognize whitebark pine as a valid species and, therefore, a listable entity under the Act. Because whitebark pine is a plant species, our policy on distinct population segments is not applicable, and, therefore, the entire range of the species within the United States and Canada is the entity evaluated in our SSA report and considered in this listing determination.

Whitebark pine has a broad range both latitudinally (occurring from a southern extent of approximately 36° north in California to 55° north latitude in British Columbia, Canada) and longitudinally (occurring from approximately 128° west in British Columbia, Canada, to an eastern extent of 108° west in Wyoming). Whitebark pine typically occurs on cold and windy high-elevation or high-latitude sites in western North America, although it also occurs in scattered areas of the warm and dry Great Basin (Service 2018, p. 13).

Rangewide, whitebark pine occurs on an estimated 32,616,422 hectares (ha) (80,596,935 acres (ac)) in western North America. Roughly 70 percent of the species' range occurs in the United States, with the remaining 30 percent of its range occurring in British Columbia and Alberta, Canada. In Canada, the majority of the species' distribution occurs on federal or provincial crown lands (COSEWIC 2010, p. 12). In the United States, approximately 88 percent of land where the species occurs is federally owned or managed. The majority is located on U.S. Forest Service (USFS) lands (approximately 74 percent). The bulk of the remaining acreage is located on National Park Service (NPS) lands (approximately 10 percent). Small amounts of whitebark pine also can be found on Bureau of Land Management lands (approximately 4 percent). The remaining 12 percent of the species' range is under non-Federal ownership, on State, private, and Tribal lands (Service 2018, pp. 14–15).

There are four stages in the life cycle of the whitebark pine: Seed, seedling,

sapling, and mature trees (*i.e.,* reproductive adults). Whitebark pine trees may produce both male and female cones, are considered reproductive at approximately 60 years of age, and can survive on the landscape for hundreds of years (Service 2018, p. 19). Primary seed dispersal occurs almost exclusively by Clark's nutcrackers (*Nucifraga columbiana*), a bird in the family Corvidae (whose members include ravens, crows, and jays) (Lanner 1996, p. 7; Schwandt 2006, p. 2). Whitebark pine trees are typically 5 to 20 meters (m) (16 to 66 feet (ft)) tall with a rounded or irregularly spreading crown shape. Whitebark pine is considered both a keystone and a foundation species in western North America, where it increases biodiversity and contributes to critical ecosystem functions (Tomback *et al.* 2001, pp. 7–8).

In general, whitebark pine has similar requirements to other tree species. That is, all four life stages require adequate amounts of sunlight, water, and soil for survival and reproduction (mature trees only). The needs of each life stage are described further in the SSA report (Service 2018, table 1, p. 23), and include Clark's nutcrackers, a lack of seed predators, cold stratification, ground fires or other disturbance, open space and limited shading, suitable temperatures and precipitation, and available nitrogen and phosphorous. Whitebark pine is a hardy conifer that tolerates poor soils, steep slopes, and windy exposures; it is found at alpine tree line and subalpine elevations throughout its range (Tomback *et al.* 2001, pp. 6, 27). Whitebark pine is slow-growing and relatively shade-intolerant, and can be outcompeted and replaced by more shade-tolerant trees in the absence of disturbances like fire (Arno and Hoff 1989, p. 6). The species grows under a wide range of annual precipitation amounts, from about 51 to over 254 centimeters (cm) (20 to 100 inches (in.)) per year, and it is considered relatively drought-tolerant (Arno and Hoff 1989, p. 7; Farnes 1990, p. 303). There are a variety of soil types that support whitebark pine (Weaver 2001, pp. 47–48; Keane *et al.* 2012, p. 3). These soil types are generally described as well-drained soils that are poorly developed, coarse, rocky, and shallow over bedrock (COSEWIC 2010, p. 10).

Seeds of whitebark pine are typically cached by seed predators such as the Clark's nutcracker. Seed predation plays a major role in whitebark pine population dynamics, as seed predators largely determine the fate of seeds. However, whitebark pine has coevolved with seed predators and has several adaptations, like masting (regional synchrony of mass production of seeds), that has allowed the species to persist despite heavy seed predation (Lorenz *et al.* 2008, pp. 3–4). Whitebark pine trees usually do not produce large cone crops until 60 to 80 years of age (Krugman and Jenkinson 1974, as cited in McCaughey and Tomback 2001, p. 109), with average earliest first cone production at 40 years of age (Tomback and Pansing 2018, p. 7). Therefore, the generation time of whitebark pine is approximately 40 to 60 years (Tomback and Pansing 2018, p. 7; COSEWIC 2010, p. v).

Whitebark pine is almost exclusively dependent upon the Clark's nutcracker for seed dispersal. Clark's nutcrackers are able to assess cone crops, and if there are insufficient seeds to cache, they will emigrate in order to survive (McKinney *et al.* 2009, p. 599). A threshold of approximately 1,000 cones per ha (2.47 ac) is needed for a high likelihood of seed dispersal by Clark's nutcrackers, and this level of cone production occurs in forests with a live basal area (the volume of wood occurring in a given area) greater than 5 square meters per ha (McKinney *et al.* 2009, p. 603). Therefore, at the population level, whitebark pine populations need sufficient density and abundance of reproductive individuals to facilitate masting and to attract Clark's nutcrackers, in order to achieve adequate recruitment and maintain resiliency to stochastic (random or unpredictable) events (Service 2018, pp. 27–28). At the species-level, for long-term viability, whitebark pine requires multiple (redundancy), self-sustaining populations (resiliency) distributed across the landscape (representation) to maintain the ecological and genetic diversity of the species (Service 2018, pp. 29–30).

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an ''endangered species'' or a ''threatened species.'' The Act defines an endangered species as a species that is ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as a species that is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The Act requires that we determine whether any species is an ''endangered species'' or a ''threatened species'' because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species—such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened

species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term foreseeable future extends only so far into the future as the Services can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Summary of Biological Status and Threats

The Act directs us to determine whether any species is an endangered species or a threatened species because of any factors affecting its continued existence. We completed a comprehensive assessment of the biological status of the whitebark pine, and prepared a report of the assessment (SSA report, Service 2018), which provides a thorough account of the species' overall viability. We define viability here as the ability of the species to persist over the long term (*i.e.,* to avoid extinction). In the discussion below, we summarize the conclusions of that assessment, which we provide in full under Docket No. FWS–R6–ES–2019–0054 on *http://www.regulations.gov* and at *https://www.fws.gov/mountain-prairie/es/whitebarkPine.php.*

We focused our analysis of whitebark pine's viability on four main stressors: Altered fire regimes, white pine blister rust, mountain pine beetle, and climate change. We focused on these four stressors because, according to the best available data, these stressors are the leading factors attributed to the decline of whitebark pine (Keane and Arno 1993, p. 44; Tomback *et al.* 2001, p. 13; COSEWIC 2010, p. 24; Tomback and Achuff 2010, p. 186; Keane *et al.* 2012, p. 1; Mahalovich 2013, p. 2; Mahalovich and Stritch, 2013, entire; Smith *et al.* 2013, p. 90; GYWPMWG 2016, p. v; Jules *et al.* 2016, p. 144; Perkins *et al.* 2016, p. xi; Shanahan *et al.* 2016, p. 1; Shepard *et al.* 2018, p. 138). While all of these stressors impact the species, we found that white pine blister rust is the main driver of the species' current and future conditions. Each of these stressors is described in detail in our SSA report (Service 2018), and is summarized below.

Altered Fire Regimes

Fire is one of the most important landscape-level disturbance processes within high-elevation whitebark pine forests (Agee 1993, p. 259; Morgan and Murray 2001, p. 238; Spurr and Barnes 1980, p. 422). Fires in the high-elevation ecosystem of whitebark pine can be of low intensity, high intensity, or mixed intensity. These varying intensity levels result in very different impacts to whitebark pine communities. Without regular disturbance, primarily from fire, these forest communities follow successional pathways that eventually lead to climax communities dominated by shade-tolerant conifers, to the exclusion of whitebark pine (Keane and Parsons 2010, p. 57). Fire also creates sites that are suitable for the Clark's nutcracker's seed-caching behavior and provides optimal growing conditions for whitebark pine (Tomback *et al.* 2001, p. 13). Low-intensity ground fires occur frequently under low-fuel conditions. These fires remove small-diameter, thin-barked seedlings and allow large, mature whitebark pine trees to thrive (Arno 2001, p. 82), as long as the mature trees are not subjected to bole (main stem of the tree) scorching (*e.g.,* Hood *et al.* 2008). Whitebark pine also has a thinner crown and a deeper root system than many of its competitors, which can allow it to withstand low-intensity fires better (Arno and Hoff 1990 in Keane and Parsons 2010, p. 58). Conversely, whitebark pine cannot survive high-severity fires; during such fires, all age and size classes can be killed. High-intensity fires, often referred to as stand replacement fires, or crown fires (Agee 1993, p. 16), produce intense heat, resulting in the removal of all or most of the vegetation from the ground (*i.e.,* high severity). Newly burned areas can provide a seedbed for whitebark pine, and if stands of unburned cone-producing whitebark pine are nearby (*i.e.,* within the range of Clark's nutcracker's seed-caching behavior), Clark's nutcrackers will cache those seeds on the burned site, and regeneration is likely. However, the introduction of white pine blister rust and the recent epidemic of the predatory mountain pine beetle (see discussion below) have reduced or effectively eliminated whitebark pine seed sources on a landscape scale, meaning that regeneration of whitebark pine following high-severity fire is unlikely in many cases (Tomback *et al.* 2008, p. 20; Leirfallom *et al.* 2015, p. 1601).

Fire exclusion policies have had unintended negative impacts on whitebark pine populations (Keane 2001a, entire). Stands once dominated by whitebark pine have undergone succession to more shade-tolerant conifers (Arno *et al.* 1993 in Keane *et al.* 1994, p. 225; Flanagan *et al.* 1998, p. 307). However, we do not know at what scale the impacts of fire exclusion and resultant forest succession have affected whitebark pine. In general, wildfire characteristics across the range of whitebark pine are expected to shift with future climate changes. Substantial increases in fire season length, number of fires, area burned, and intensity are predicted (reviews in Keane *et al.* 2017, pp. 34–35, and Westerling 2016, pp. 1–2). For a more detailed discussion of the impacts of fire on whitebark pine, see the SSA report (Service 2018, pp. 31–34).

White Pine Blister Rust

White pine blister rust is a fungal disease of five-needle pines caused by a nonnative pathogen, *Cronartium ribicola* (Geils *et al.* 2010, p. 153). The fungus was inadvertently introduced around 1910, near Vancouver, British Columbia (McDonald and Hoff 2001, p. 198; Brar *et al.* 2015, p. 10). The incidence of white pine blister rust at stand, landscape, and regional scales varies due to time since introduction and environmental suitability for its development. It continues to spread into areas originally considered less suitable for infection, such as the Sierra Nevada Mountains, and it has become a serious threat, causing severe population losses to several species of western pines, including whitebark pine (Schwandt *et al.* 2010, pp. 226–230). Its current known geographic distribution in western North America includes all U.S. States and British Columbia and Alberta, Canada.

The white pine blister rust fungus has a complex life cycle: It does not spread directly from one tree to another, but alternates between primary hosts (*i.e.,* five-needle pines) and alternate hosts. Alternate hosts in western North America are typically woody shrubs in the genus *Ribes* (gooseberries and currants) (McDonald and Hoff 2001, p. 193; McDonald *et al.* 2006, p. 73). The

spreading of white pine blister rust spores depends on the distribution of hosts, the prevailing microclimates, and the different genotypes of white pine blister rust and hosts (McDonald and Hoff 2001, pp. 193, 202). A wave event (a massive spreading of new white pine blister rust infections into new or relatively unaffected areas, or intensification of spread from a cumulative buildup in already infected stands) occurs where alternate hosts are abundant and when late summer weather is favorable to spore production and dispersal, and subsequent infection of pine needles. Because its abundance is influenced by weather and host populations, white pine blister rust also is affected by climate change. If conditions become cooler or moister, white pine blister rust will likely spread and intensify; conversely, where conditions become both warmer and drier, it may spread more slowly (Service 2018, p. 39). However, even if climatic conditions slow the spread of white pine blister rust, it remains ever-present on the landscape, infecting seedlings that attempt to reestablish.

White pine blister rust attacks whitebark pine seedlings, saplings, and mature trees, damaging stems and cone-bearing branches and restricting nutrient flows; it eventually girdles branches and boles (tree trunks or stems), leading to the death of branches or the entire tree (Tomback *et al.* 2001, p. 15, McDonald and Hoff 2001, p. 195). While some infected mature trees can continue to live for decades (Wong and Daniels 2017, p. 1935), their cone-bearing branches typically die first, thereby eliminating the seed source required for reproduction (Geils *et al.* 2010, p. 156). Although some areas of the species' range have been impacted by white pine blister rust for 90 years or more, for whitebark pine that timeframe equates to only 1.5 generations (Mahalovich 2013, p. 17), which means the species has had a limited time to adapt to or develop resistance to white pine blister rust. However, low levels of rust resistance have been documented on the landscape in individual trees and their seeds, indicating that there is some level of heritable resistance to white pine blister rust (Hoff *et al.* 2001, p. 350; Mahalovich *et al.* 2006, p. 95; Mahalovich 2015, p. 1). In some populations and geographic areas, there is moderate frequency and level of genetic resistance, while in others, the frequency of resistance appears to be much lower (Sniezko 2018, p. 1–2).

Most current management and research focuses on producing and planting whitebark pine seedlings with proven genetic resistance to white pine blister rust, but also includes enhancing natural regeneration and applying silvicultural treatments, such as appropriate site selection and preparation, pruning, and thinning (Zeglen *et al.* 2010, p. 347). However, management challenges to restoration include remoteness, difficulty of access, and a perception that some whitebark pine restoration activities conflict with wilderness values (Schwandt *et al.* 2010, p. 242). In addition, the vast scale at which planting rust-resistant trees would need to occur, long timeframes in which restoration efficacy could be assessed, and limited funding and resources will make it challenging to restore whitebark pine throughout its range. Based on modeling results (Ettl and Cottone 2004, pp. 36–47; Hatala *et al.* 2011; Field *et al.* 2012, p. 180), we conclude that, in addition to the ubiquitous presence of white pine blister rust across the entire range of the whitebark pine, white pine blister rust infection likely will continue to increase and intensify within individual sites, ultimately resulting in stands that are no longer viable and that potentially face extirpation. For a more detailed discussion of white pine blister rust, see the SSA report (Service 2018, pp. 35–42).

Mountain Pine Beetle

The native mountain pine beetle (*Dendroctonus ponderosae* Hopkins) is one of the principal sources of whitebark pine mortality (Raffa and Berryman 1987, p. 234; Arno and Hoff 1989, p. 7). Mountain pine beetles feed on whitebark pine and other western conifers, and to reproduce successfully, the beetles must kill host trees (Logan and Powell 2001, p. 162; Logan *et al.* 2010, p. 895). At endemic, or more typical levels, mountain pine beetles remove relatively small areas of trees, changing stand structure and species composition in localized areas. However, when conditions are favorable (abundant hosts and favorable climate), mountain pine beetle populations can erupt to epidemic levels and create stand-replacing events that may kill 80 to 95 percent of suitable host trees (Berryman 1986 as cited in Keane *et al.* 2012, p. 26). Such outbreaks are episodic, and typically subside only when suitable host trees have been exhausted or temperatures are sufficiently low to kill larvae and adults (Gibson *et al.* 2008, p. 2). Therefore, at epidemic levels, mountain pine beetle outbreaks may have population-level effects on whitebark pine.

Mountain pine beetle epidemics affecting whitebark pine have occurred throughout recorded history (Keane *et al.* 2012, p. 26). The most recent mountain pine beetle epidemic began in the late 1990s, and although it has since subsided, it continues to be a measurable but much reduced source of mortality for whitebark pine (Macfarlane *et al.* 2013, p. 434; Mahalovich 2013, p. 21; Shelly 2014, pp. 1–2). Unlike previous epidemics, the most recent mountain pine beetle outbreak had a significant rangewide impact on whitebark pine (Logan *et al.* 2003, p. 130; Logan *et al.* 2010, p. 898; MacFarlane *et al.* 2013, p. 434). Trends of environmental effects from climate change have provided favorable conditions necessary to sustain the most recent, unprecedented mountain pine beetle epidemic in high-elevation communities across the western United States and Canada (Logan and Powell 2001, p. 167; Logan *et al.* 2003, p. 130; Raffa *et al.* 2008, p. 511). This most recent epidemic is waning across the majority of the range (Hayes 2013, pp. 3, 41, 42, 54; Alberta Whitebark and Limber Pine Recovery Team 2014, p. 18; Bower 2014, p. 2; Shelly 2014, pp. 1–2). However, given ongoing and predicted environmental effects from climate change, we expect mountain pine beetles will continue to expand into higher elevation habitats and that epidemics will continue within the range of whitebark pine (Buotte *et al.* 2016, p. 2516; Sidder *et al.* 2016, p. 9). For a more detailed discussion of mountain pine beetle, see the SSA report (Service 2018, pp. 42–49).

Climate Change

Our analyses under the Act include consideration of ongoing and projected changes in climate. In general, the pace of predicted climate change will outpace many plant species' abilities to respond to the concomitant habitat changes. Whitebark pine is potentially particularly vulnerable to warming temperatures because it is adapted to cool, high-elevation habitats. Therefore, current and anticipated warming is expected to make its current habitat unsuitable for whitebark pine, either directly or indirectly as conditions become more favorable to whitebark pine competitors, such as subalpine fir or mountain hemlock (Bartlein *et al.* 1997, p. 788; Hamann and Wang 2006, p. 2783; Hansen and Phillips 2015, p. 74; Schrag *et al.* 2007, p. 8; Warwell *et al.* 2007, p. 2; Aitken *et al.* 2008, p. 103; Loehman *et al.* 2011, pp. 185–187; Rice *et al.* 2012, p. 31; Chang *et al.* 2014, p. 10).

The rate of migration needed to respond to predicted climate change will be significant (Malcolm *et al.* 2002,

pp. 844–845; McKenney *et al.* 2007, p. 941). It is not known whether whitebark pine is capable of migrating at a pace sufficient to move to areas that are more favorable to survival given the projected effects of climate change. It is also not known the degree to which the Clark's nutcracker could facilitate this migration. In addition, the presence of significant white pine blister rust infection in the northern range of the whitebark pine could serve as a barrier to effective northward migration. Whitebark pine survives at high elevations already, so there is little remaining habitat in many areas for the species to migrate to higher elevations in response to warmer temperatures. Adaptation in response to a rapidly warming climate would also be unlikely, as whitebark pine is a long-lived species with a long generation time (Bradshaw and McNeilly 1991, p. 10).

Climate models suggest that climate change is expected to act directly and indirectly, regardless of the emission scenario, to significantly decrease the probability of rangewide persistence in whitebark pine within the next 100 years (*e.g.,* Warwell *et al.* 2007, p. 2; Hamann and Wang 2006, p. 2783; Schrag *et al.* 2007, p. 6; Rice *et al.* 2012, p. 31; Loehman *et al.* 2011, pp. 185–187; Chang *et al.* 2014, p. 10–12). This time interval is less than two generations for this long-lived species. See the Determination section of this document for our discussion on the relationship of this modeled timeframe to our determination of the foreseeable future for this listing determination. In addition, projected climate change effects are a significant threat to the whitebark pine, because the impacts of climate change, including projected temperature and precipitation changes, interact with and exacerbate other stressors such as mountain pine beetle and wildfire, resulting in habitat loss and population decline. For a more detailed discussion of climate change impacts on whitebark pine, see the SSA report (Service 2018, pp. 49–55).

Current Conditions

In order to assess the current condition of the whitebark pine across its extensive range, we broke the range into 15 smaller analysis units (AUs), based primarily on Environmental Protection Agency Level III ecoregions as well as input from whitebark pine experts, as described in the SSA report (Service 2018, pp. 57–59). Ecoregions identify areas of general similarity in ecosystems, as well as topographic and environmental variables. We further divided AUs in the United States from those in Canada to reflect differences in management and legal status. A map of these AUs is available in the SSA report (Service 2018, pp. 58, figure 9). We then evaluated the best available data regarding the current impacts of wildfire, white pine blister rust, and mountain pine beetle on the resiliency (ability to withstand stochastic events) of each AU. These analyses are described in detail in the SSA report (Service 2018, pp. 56–81), and our conclusions are summarized below. We note that not all AUs are equal in size; they encompass varying proportions of the species' range, ranging from the Middle Rockies AU (27.6 percent of the range) to the Olympics AU (0.4 percent of the range) (Service 2018, p. 59, table 3).

Resiliency

To assess the current impact of wildfire on the resiliency of whitebark pine AUs, we examined burn data collected from 1984 to 2016 from the following sources Monitoring Trends in Burn Severity [MTBS] (a multi-agency program compiling fire data from multiple sources including USGS and the USFS); GeoMac (a multi-agency program providing fire data from multiple agencies managed by USGS); and the Canadian Forest Service (Service 2018, p. 60). We found that from 1984 to 2016, between 0.08 percent and 42.64 percent of each AU burned (including burns of any severity level). Although we collected information on all fires, our analysis focuses on areas of high burn severity that could potentially negatively impact the species. Overall, a minimum of 1,273,583 ha (3,147,092 ac) of whitebark pine habitat burned in high severity fires during this time period, equating to approximately 5 percent of the species' range within the United States (Service 2018, pp. 60–63). Similar data for high severity fires were not available for AUs in Canada.

To assess the current impact of white pine blister rust on the resiliency of whitebark pine AUs, we examined the large volume of published literature and information provided by experts, as described in the SSA report (Service 2018, pp. 63–71). White pine blister rust infections have increased in intensity over time and are now prevalent even in trees living in cold, dry areas formerly considered less susceptible (Tomback and Resler 2007, p. 399; Smith-Mckenna *et al.* 2013, p. 224), such as the Greater Yellowstone Ecosystem. This trend has resulted in reduced seed production and increased mortality. We assessed the current impact of white pine blister rust on whitebark pine by evaluating data from a modeled dataset developed by the USFS in 2011 for the United States. This modeled dataset is based on white pine blister rust infection information from the USFS Whitebark and Limber Pine Information System (WLIS) database combined with environmental variables (Service 2018, p. 68–69). Canadian white pine blister rust data were derived from a combination of survey data from Parks Canada and empirical literature (*e.g.,* COSEWIC 2010, p. viii and Table 4, p. 19; Smith *et al.* 2010, p. 67; Smith *et al.* 2013, p. 90; Shepherd *et al.* 2018, p. 6). Approximately 34 percent of the range is infected with white pine blister rust (Service 2018, p. 93), and every AU within the whitebark pine's range is currently affected by the disease. The current average white pine blister rust infection level within each AU ranges between 2 percent and 74 percent, with 12 of the 15 AUs having an average infection level over 20 percent, and 5 of the AUs having average infection levels above 40 percent (Service 2018, pp. 68–71). Average infection levels are lowest in the southern AUs (Klamath Mountains, Basin and Range, and Sierras) and then sharply increase moving north into the latitudes of the Rocky Mountains and Cascades. As stated above, once white pine blister rust is present in an area, there are no known methods to eradicate it. It will spread and infect more of the area when conditions are favorable.

To assess the current impact of mountain pine beetle on the resiliency of whitebark pine AUs, we aggregated aerial detection survey (ADS, a USFS dataset) data for the United States and aerial overview survey (AOS, a dataset of the British Columbia Ministry of Forests) data for Canada from 1991 through 2016 across the range of the whitebark pine (Service 2018, p. 71). As mountain pine beetles only attack mature trees, the effects of mountain pine beetle attacks observed during aerial surveys can be interpreted as the loss of seed-producing trees. From 1991 through 2016, 5,919,276 ha (14,626,850 ac) of the whitebark pine's range have been impacted by the mountain pine beetle, resulting in at least 18 percent of the whitebark pine's range being negatively impacted (Service 2018, pp. 71–75). Similar to white pine blister rust infection, the more southern AUs are currently less impacted by the mountain pine beetle than their more northern counterparts. On the West Coast, the Cascades, Thompson Plateau, and Fraser Plateau AUs have had at least 25 percent of the whitebark pine's range impacted by the mountain pine beetle.

Overall, whitebark pine stands have seen severe reductions in reproduction

and regeneration because of these stressors, thus resulting in a reduction in resiliency and therefore their ability to withstand stochastic events. High severity wildfires, white pine blister rust, and mountain pine beetle all act on portions of whitebark pine's range, killing individuals and limiting reproduction and regeneration (Service 2018, p. 81, Figure 14). Interactions between these factors have further exacerbated the species' decline and have reduced its resiliency.

Representation

Having evaluated the current impact of the above stressors on the resiliency of each whitebark pine AU, we next evaluated the species' current levels of representation, or ability to adapt to changing conditions (Service 2018, pp. 75–78). The range of variation found within a species, which may include ecological, genetic, morphological, and phenological diversity, may be an indication of its levels of representation. Whitebark pine can be found in a number of ecological settings throughout its range, mainly depending on elevation, latitude, and climate of an area. Whitebark pine has high genetic diversity relative to other conifer tree species (*i.e.,* high representation in terms of genetic variation), with poor genetic differentiation among zones, and similar levels of diversity to other highly geographically distributed tree species in North America (Mahalovich and Hipkins 2011, p. 126). The high levels of genetic diversity within the species may be impacted through bottleneck events caused by mortality resulting from white pine blister rust, mountain pine beetle, or fires. Whitebark pine also has higher rates of inbreeding than most other wind-pollinated conifers, likely due to the close proximity of mature trees arising from clumps of seeds of related individuals or even from the same cone, suggesting that population genetic structure is driven by seed dispersal by the Clark's nutcracker (Keane *et al.* 2012, p. 14). The whitebark pine exhibits a range of morphologies, from tall, single-stemmed trees to shrub-like krummholz forms. These factors may contribute to the species' level of ability to adapt to changing conditions. Given the species wide geographic range and levels of ecological, genetic, morphological, and phenological diversity, it likely has inherently higher levels of representation than many species.

Redundancy

Finally, we evaluated the whitebark pine's current levels of redundancy, or ability to withstand catastrophic events. Whitebark pine is widely distributed, and thus inherently has higher levels of redundancy than many species. Rangewide, whitebark pine occurs on an estimated 32,616,422 ha (80,596,935 ac) in western North America. However, as a result of the rangewide reduction in resiliency due to the stressors discussed above, there has been a concomitant loss in species redundancy, as many areas become less able to contribute to the species' ability to withstand catastrophic events (Service 2018, p. 78).

Overall, rangewide data from USFS Forest Inventory and Analysis surveys indicate that 51 percent of all standing whitebark pine trees in the United States are now dead, with over half of that amount occurring approximately in the last two decades alone (Goeking and Izlar 2018, p. 7). Each of the stressors acts individually and cumulatively on portions of the whitebark pine's range, and interactions between stressors have further exacerbated the species' decline and have reduced its resiliency. This reduction in resiliency is rangewide, occurring across all AUs, with the Canadian, U.S., and Northern Rockies likely the most impacted. While the species is still wide-ranging and, therefore, has inherently higher levels of representation and redundancy than many species, reductions to resiliency across the range are reducing the species' adaptive capacity and ability to withstand catastrophic events (Service 2018, pp. 78–80).

Future Conditions

To assess the future condition of whitebark pine, we projected the impacts of each of the stressors described above under three plausible scenarios (scenarios 1, 2, and 3, as noted below). This analysis, and the uncertainties associated with it, are described in more detail in the SSA report (Service 2018, pp. 82–114), and are summarized below. Scenarios constructed include variation in:

(1) The presence of white pine blister rust. Given historical trends, we assume in all scenarios that white pine blister rust will continue to spread and intensify throughout the range of whitebark pine. There is no information to suggest that the rate of spread or prevalence of white pine blister rust will decrease in the future. The incidence of white pine blister rust at stand, landscape, and regional scales varies due to time since introduction and environmental suitability for its development. It continues to spread into areas originally considered less suitable for persistence, and it has become a serious threat. In our future scenarios, we varied the future rate of white pine blister rust spread between one and four percent annually based on values presented in the literature (*e.g.,* Schwandt et al. 2013; Smith et al 2013). The percentage of genetically resistant individuals and the effectiveness and scale of management efforts to collect, propagate, and plant genetically resistant individuals are key areas of uncertainty. Therefore, we varied the level of genetic resistance between a lower value of 10 percent and higher value of 40 percent based on a range of values presented in the literature (*e.g.,* Mahalovich 2013, p. 33). We considered the higher 40 percent value to include both the presence of some level of natural resistance and planting of resistant individuals.

(2) The frequency of high severity wildfire. Given current trends and predictions for future changes in the climate, we assume in all scenarios that the frequency of stand replacing wildfire will increase although the magnitude of that increase is uncertain (Keane *et al.* 2017, p. 18; Westerling 2016, entire; Littell et al. 2010, entire). Because of that uncertainty, we choose what are likely conservative values of a 5 or 10 percent increase in severe wildfire above current annual levels.

(3) The magnitude of future mountain pine beetle impacts. Given warming trends, we assume in all scenarios that mountain pine beetle epidemics will continue to impact whitebark pine in the future. There is no information to suggest that mountain pine beetle epidemics will decrease in magnitude or frequency in the future. In our future scenarios, we predicted a new mountain pine beetle epidemic would occur every 60 years, as that is the minimum time it would likely take for individual trees to achieve diameters large enough to facilitate successful mountain pine beetle brood production that is required to reach epidemic levels.

Climate change is understood to impact whitebark pine principally through its effect on the magnitude of the other three key stressors, and was therefore included in these projections as an indirect impact to whitebark pine resilience by modifying the rate of change in the other stressors (Service 2018, p. 82). Similarly, potential levels of current and future conservation efforts were also included indirectly in these projections by varying the rate of change of those stressors for which conservation could potentially have an effect. Due to the longevity and long generation time of the species, we modeled projections of impacts for several timeframes, going out 180 years,

which corresponds to approximately three generations of whitebark pine (Tomback and Pansing 2018, p. 7; COSEWIC 2010, p. v). However, we focused our discussion of viability in the SSA report largely on the 60-year (1 generation) timeframe where our confidence is greatest with respect to the range of plausible projected changes to stressors and the species' response. We note that our projections are based on long-term geospatial data sets and a large body of empirical data, and the scenarios chosen encompass the full range of conditions that could plausibly occur. Below, we briefly summarize each scenario that we considered, and the results of our analysis under each scenario.

Scenario 1 is a continuation of current trends, where impacts from high severity fires and mountain pine beetle continue at current levels. We predicted a new mountain pine beetle epidemic would occur every 60 years, as that is the minimum time it would likely take for individual trees to achieve diameters large enough to facilitate successful mountain pine beetle brood production that is required to reach epidemic levels. In this scenario, white pine blister rust begins at the current estimated proportion of the range infected and spreads at 1 percent per year with an assumed 10 percent level of genetically resistant individuals (Service 2018, p. 89).

In scenario 2, high severity wildfires increase by 5 percent over current trends. The spread of white pine blister rust continues at a relatively low annual rate (1 percent per year), and the assumed level of genetic resistance to white pine blister rust is relatively high at 40 percent (a value that includes both the presence of some level of natural resistance and planting of resistant individuals). Mountain pine beetle epidemics continue to occur at 60-year intervals, but with 20 percent recruitment of whitebark pine into the population between epidemics (Service 2018, p. 90).

In scenario 3, high severity wildfires increase by 10 percent over current trends. The spread of white pine blister rust increases (4 percent per year), and only 10 percent of individuals on the landscape have genetic resistance to white pine blister rust. Mountain pine beetle epidemics continue to occur at 60-year intervals, but impacts increase in severity by 10 percent, and there is no recruitment between epidemics (Service 2018, p. 90).

Under each scenario, we evaluated what percentage of the whitebark pine's range would be impacted by each stressor, relative to current levels. We focused our discussion of viability in the SSA report largely on the 60-year (1 generation) timeframe where our confidence is greatest with respect to the range of plausible projected changes to stressors and the species' response. See the Determination section of this document for our discussion on the relationship of this modeled timeframe to our determination of the foreseeable future for this listing determination. Within this timeframe, a continuation of current trends in high severity fires (under scenario 1) would not likely severely negatively impact whitebark pine resiliency, redundancy, or representation in the absence of other threats, as newly burned areas can potentially provide a seedbed for whitebark pine if stands of healthy cone-producing whitebark pine are nearby, resulting in some level of natural regeneration. Similarly, if current trends in high severity fires continue or increase by 5 to 10 percent (the relatively small projected increase in severe wildfire under scenarios 2 and 3), high severity fires alone (in the absence of other threats) would not be likely to severely negatively impact whitebark pine (Service 2018, pp. 100–101).

Currently, approximately 34 percent of the range is infected by white pine blister rust. Within the 60-year timeframe, under scenario 1, approximately 61 percent of the range will be infected with white pine blister rust. Under scenario 2, approximately 52 percent of the range will be infected within the next 60 years. Under scenario 3, approximately 88 percent of the range will be infected within the next 60 years (Service 2018, pp. 101–103).

In addition, approximately 17 percent of the range is currently impacted by mountain pine beetle. Within the 60-year timeframe, under scenario 1, an estimated 31 percent of the range will be impacted by the mountain pine beetle in the absence of other stressors. Under scenario 2, an estimated 15 percent of the range will be impacted by the mountain pine beetle within 60 years. Under scenario 3, approximately 40 percent of the range will be impacted by the mountain pine beetle within 60 years (Service 2018, pp. 103–105). These results are further broken down by AU in the SSA report (Service 2018, pp. 100–105).

Although not specifically addressed in our projections, the best available science indicates that there are strong synergistic and cumulative interactions between the four key stressors (mountain pine beetle, white pine blister rust, severe fire, and climate change), which will increase negative impacts to whitebark pine under all three scenarios. Therefore, our assessment of the future effects of each individual stressor on whitebark pine likely underestimates the total impact of these stressors when combined on the species' overall viability. For example, environmental changes resulting from climate change are expected to alter fire regimes, resulting in decreased fire intervals and increased fire severity. More frequent stand-replacing fires will likely negatively impact whitebark pine resiliency by reducing the probability of regeneration in many areas (Tomback *et al.* 2008, p. 20; Leirfallom *et al.* 2015, p. 1601). Warming trends have also resulted in unprecedented mountain pine beetle epidemics throughout the range of the whitebark pine (Logan *et al.* 2003, p. 130; Logan *et al.* 2010, p. 896). In addition, the latest mountain pine beetle epidemic and white pine blister rust together have negatively impacted the probability of whitebark pine regeneration because both have acted to severely decrease seed cone production. These and other interactions are described in the SSA report (Service 2018, pp. 105–111).

In summary, the abundance of whitebark pine is forecasted to decline over time under all three scenarios we considered. In these scenarios, the rate of decline appeared to be most sensitive to the rate of white pine blister rust spread, the presence of genetically resistant individuals (whether natural or due to conservation efforts), and the level of regeneration (Service 2018, pp. 111–112). Whitebark pine viability has declined over time, and continuation of current trends and synergistic and cumulative interactions between wildfire, white pine blister rust, mountain pine beetle, and climate change will continue to result in actual or functional loss of populations. However, we acknowledge that there may be significant differences and a large degree of variation when examining stressors at smaller landscape or stand scales. As a result of the highly heterogeneous ecological settings of this widespread species (*e.g.,* differences in topography, elevation, weather, and climate) and geographic variation in levels of genetic resistance to white pine blister rust, rates of whitebark pine decline will likely vary for each AU.

We predict all AUs will have a reduced level of resiliency in the future. This reduction in resiliency will be the result of continued increase in white pine blister rust infection, synergistic and cumulative interactions between white pine blister rust and other stressors, and the resulting loss of seed

source and subsequent regeneration. Whitebark pine remains widely distributed across the spatial extent and ecological settings of its historical range. However, under all three future scenarios, we predict redundancy and representation will decline, as fewer populations persist and the spatial extent and connectivity of the species declines (Service 2018, pp. 112–113).

See the SSA report (Service 2018, entire) for a more detailed discussion of our evaluation of the biological status of the whitebark pine and the influences that may affect its continued existence. Our conclusions in the SSA report, which form the basis for the determination below, are based upon the best available scientific and commercial data.

Management and Restoration

There are a variety of regulatory mechanisms, as well as management and restoration plans in place, that benefit or impact whitebark pine, as described in the SSA report (Service 2018, appendix A). Due to the broad distribution of whitebark pine in the United States and Canada, management of this species falls under numerous jurisdictions that encompass a spectrum of local and regional ecological, climatic, and management conditions and needs. Several management and restoration plans have been developed for specific regions or jurisdictions to address the task of conserving and restoring this widespread, long-lived species (Service 2018, p. 112). Conversely, some areas within the range of whitebark pine do not have a specific management plan for whitebark pine (*e.g.,* central Idaho) (Service 2018, p. 112). Consequently, within the United States management actions in these areas would generally follow established forest or vegetation management plans developed under the National Forest Management Act of 1976 (16 U.S.C. 1600 *et seq.*) or other similar policies (*e.g.,* National Forest land management plans, National Park Service vegetation management plans). In Canada, the Committee on the Status of Endangered Wildlife designated whitebark pine as Endangered under the Canadian Species at Risk Act (SARA) on June 20, 2012, due to the high risk of extirpation. This listing provides protection from harming, killing, collecting, buying, selling or possessing, for individuals on Canadian Federal land.

See the SSA report for a description of management and restoration plans currently in place or under development, and some of their accomplishments (Service 2018, appendix A). Many of these efforts have had positive impacts on the species on local or regional scales. However, given the vast geographic range of the species and the ubiquitous presence of white pine blister rust, there is currently no effective means to control the disease and its cumulative impacts with other stressors on a species-wide scale through any regulatory or nonregulatory mechanism.

Twenty-nine percent of the range of whitebark pine within the United States (Service 2018, p. 15) is designated wilderness under the Wilderness Act of 1964 (16 U.S.C. 1131–1136). The Wilderness Act states that wilderness should be managed to preserve its natural conditions and yet remain untrammeled by humans. This designation limits management options and conservation efforts in those areas to some degree. How the Wilderness Act is implemented can vary between agencies, regions, or even between species. While the Wilderness Act allows for some ''minimal actions'' to address certain management needs, it does not directly allow for treatment of the impacts of white pine blister rust, fire exclusion policies, mountain pine beetle epidemics, or climate change. For a more detailed discussion of how the Wilderness Act influences the management of whitebark pine, see the SSA report (Service 2018, pp. 129–130).

Determination of Whitebark Pine Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of ''endangered species'' or ''threatened species.'' The Act defines ''endangered species'' as a species ''in danger of extinction throughout all or a significant portion of its range,'' and ''threatened species'' as a species ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The Act requires that we determine whether a species meets the definition of ''endangered species'' or ''threatened species'' because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Status Throughout All of Its Range

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the whitebark pine across its range in the United States and Canada. Our analysis of the current and future condition of whitebark pine found that the species is being impacted by four main stressors: Altered fire regimes (Factor E), white pine blister rust (Factor C), mountain pine beetle (Factor C), and climate change (Factor E). We found white pine blister rust (Factor C) to be the main driver of the species' current and future condition. White pine blister rust is currently ubiquitous across the range, and under all three future condition scenarios, it is expected to expand significantly. Under the three scenarios, within one generation, 52 to 88 percent of the range will be infected. The impacts of white pine blister rust combined with other stressors will reduce the ability of whitebark pine stands to regenerate (*i.e.,* resiliency) following disturbances, such as fire and mountain pine beetle outbreaks. The decline is expected to be most pronounced in the northern two-thirds of the whitebark pine's range, where white pine blister rust infection rates are predicted to be highest. Despite the existing regulatory mechanisms (Factor D) and voluntary conservation efforts described above, these stressors have continued to spread and are predicted to increase in prevalence in the future. Our analysis did not find any stressors to be impacting the species at a population or species level under Factors A or B.

After evaluating threats to the species and assessing the cumulative effect of the threats under the section 4(a)(1) factors, we find that the whitebark pine is likely to become endangered throughout all of its range within the foreseeable future. This finding is based on anticipated reductions in resiliency, redundancy, and representation in the future as a result of continued increase in white pine blister rust infection and associated mortality, synergistic and cumulative interactions between white pine blister rust and other stressors, and the resulting loss of seed source. White pine blister rust is already ubiquitous rangewide, and there is currently no effective method to reverse it on a meaningful scale. In addition, 51 percent of whitebark pine trees in the United States are now dead (Goeking and Izlar 2018, p. 7). For this long-lived species, we consider the foreseeable future to be within 40 to 80 years. This timeframe encompasses the length of approximately one generation (*i.e.,* 60 years) for whitebark pine, but also accounts for uncertainty in the precise rate of spread of white pine blister rust

and associated mortality. While we were able to project the species response out to 180 years in our SSA, our confidence is greatest with respect to the range of plausible projected changes to stressors and the species' response under 80 years. We can reasonably determine that both the future threats and the species' responses to those threats are likely within this 40- to 80-year timeframe (*i.e.,* the foreseeable future).

We find that the whitebark pine is not currently in danger of extinction because the species is still widespread throughout its extensive range, and whitebark pine trees are expected to persist on the landscape for many decades, especially given their long lifespan, and the presence of some levels of genetic resistance to white pine blister rust. In addition, there is uncertainty regarding how quickly white pine blister rust, the primary stressor, will spread within the three southwestern AUs (the Sierras, Basin and Range, and Klamath Mountains AUs) where it currently occurs at low levels and greater levels of resiliency remain. Therefore, the species currently has sufficient redundancy and representation to withstand catastrophic events and maintain adaptability to changes, particularly in the southwestern part of the range, and is not at risk of extinction now. However, we expect that the stressors, individually and cumulatively, will reduce resiliency, redundancy, and representation within all parts of the range within the foreseeable future. Therefore, on the basis of the best available scientific and commercial information, we determine that the whitebark pine is not currently in danger of extinction, but is likely to become in danger of extinction within the foreseeable future, throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020) (*Everson*), vacated the aspect of the 2014 Significant Portion of its Range Policy that provided that the Services do not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and, (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Everson,* we now consider whether there are any significant portions of the species' range where the species is in danger of extinction now (*i.e.,* endangered). In undertaking this analysis for the whitebark pine, we will address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species may be endangered.

The statutory difference between an endangered species and a threatened species is the time frame in which the species becomes in danger of extinction; an endangered species is in danger of extinction now while a threatened species is not in danger of extinction now but is likely to become so in the foreseeable future. Thus, we reviewed the best scientific and commercial data available regarding the time horizon for the threats that are driving the whitebark pine to warrant listing as a threatened species throughout all of its range. We then considered whether these threats are geographically concentrated in any portion of the species' range in a way that would accelerate the time horizon for the species' exposure or response to the threats. We examined the following threats: Altered fire regimes, white pine blister rust, mountain pine beetle, and climate change, including synergistic and cumulative effects. We found white pine blister rust to be the main driver of the species' status.

We found a concentration of threats in the northern two-thirds of the whitebark pine's range, including the following Analysis Units: Nechako Plateau, Fraser Plateau, Thompson Plateau, Columbia Mountains, Canadian Rockies, Olympics, Cascades, Northern Rockies, Blue Mountains, Idaho Batholith, US Canadian Rockies, and Middle Rockies (see Service 2018, Figures 9, 11, 14). As described above, the impacts of white pine blister rust combined with other stressors is expected to reduce the ability of whitebark pine stands to regenerate following disturbances. Although white pine blister rust is currently ubiquitous across the range, white pine blister rust infection rates are currently the highest, and will further increase in the future, in the northern two-thirds of whitebark pine's range; as such, we expect future declines in resiliency to be most pronounced in the northern two-thirds of the whitebark pine's range.

However, despite the prevalence of white pine blister rust and other stressors in the northern two-thirds of the whitebark pine's range, whitebark pine trees are still widespread throughout this extensive geographic area. Given their long lifespan and the presence of some levels of genetic resistance to white pine blister rust, whitebark pine trees are expected to persist on the landscape for many decades. As we discuss above, white pine blister rust may not immediately kill infected trees; many trees with white pine blister rust can live for decades before they succumb to the disease. Thus, currently, levels of redundancy and representation are reduced, but sufficient to withstand catastrophic events and maintain adaptability to changes, and therefore the species is not currently in danger of extinction in this portion of the range.

However, white pine blister rust will likely continue to spread throughout the species' range in the future, reducing available seed source and recruitment into the future. We expect that white pine blister rust, individually and cumulatively along with other stressors, will reduce resiliency, redundancy, and representation within the northern two-thirds of the range such that whitebark pine is likely to become an endangered species in this portion within the foreseeable future.

Although some threats to the whitebark pine are concentrated in the northern two-thirds of the species' range, the best scientific and commercial data available does not indicate that the concentration of threats, or the species' responses to the concentration of threats, are likely to accelerate the time horizon in which the species becomes in danger of extinction in that portion of its range. As a result, the whitebark pine is not in danger of extinction now in the northern two-thirds of its range. Therefore, we determine, that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological*

Diversity v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that the whitebark pine meets the definition of a threatened species. Therefore, we propose to list the whitebark pine as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The SSA Report developed to inform this listing determination may also inform the development of the recovery outline and recovery plan, and may be updated as new information becomes available. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan and the SSA may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (''downlisting'') or removal from listed status (''delisting''), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*http://www.fws.gov/endangered*), or from our Wyoming Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands. If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Wyoming, Montana, Idaho, Washington, Oregon, California, and Nevada would be eligible for Federal funds to implement management actions that promote the protection or recovery of the whitebark pine. Information on our grant programs that are available to aid species recovery can be found at *http://www.fws.gov/grants.*

Although the whitebark pine is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the U.S. Forest Service, National Park Service, and Bureau of Land Management.

Effects of Listing

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. Based on the best available information, and considering the proposed 4(d) rule described below, the following actions are unlikely to result in a violation of section 9, if these activities are carried out in accordance with existing regulations and permit requirements; this list is not comprehensive:

- Silviculture practices and forest management activities that address fuels management, insect and disease impacts, and wildlife habitat management (*e.g.,* cone collections, planting seedlings/sowing seeds, mechanical cuttings as a restoration tool in stands experiencing advancing succession, full or partial suppression of

wildfires in whitebark pine communities, allowing wildfires to burn, or survey and monitoring of tree health status).

Based on the best available information, the following activities may potentially result in a violation of section 9 of the Act (except in the case of the exceptions listed in our proposed 4(d) rule; see discussion below); this list is not comprehensive:

- Removal and reduction to possession of the species from areas under Federal jurisdiction;
- Malicious damage or destruction of the species on any areas under Federal jurisdiction; or
- Removal, cutting, digging up, or damage or destruction of the species on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law.

For example, the removal or damage of whitebark pine trees, when not conducted or authorized by the Federal agency with jurisdiction over the land where the activity occurs, would be prohibited.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Wyoming Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

II. Proposed Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act states that the ''Secretary shall issue such regulations as he deems necessary and advisable to provide for the conservation'' of species listed as threatened. The U.S. Supreme Court has noted that very similar statutory language demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean ''the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to [the Act] are no longer necessary.'' Additionally, section 4(d) of the Act states that the Secretary ''may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants.'' Thus, regulations promulgated under section 4(d) of the Act provide the Secretary with wide latitude of discretion to select appropriate provisions tailored to the specific conservation needs of the threatened species. The statute grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have approved rules developed under section 4(d) that include a taking prohibition for threatened wildlife, or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also approved 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him with regard to the permitted activities for those species.'' He may, for example, permit taking, but not importation of such species, or he may choose to forbid both taking and importation but allow the transportation of such species, as long as the prohibitions, and exceptions to those prohibitions, will ''serve to conserve, protect, or restore the species concerned in accordance with the purposes of the Act'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

The Service has developed a proposed species-specific 4(d) rule that is designed to address the whitebark pine's specific threats and conservation needs. Although the statute does not require the Service to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this rule is necessary and advisable to provide for the conservation of the whitebark pine, as explained below. As discussed in above under Determination, the Service has concluded that the whitebark pine is at risk of extinction within the foreseeable future primarily due to the continued increase in white pine blister rust infection and associated mortality, synergistic and cumulative interactions between white pine blister rust and other stressors, and the resulting loss of seed source. The provisions of this proposed 4(d) rule would promote conservation of the whitebark pine by encouraging management of the landscape in ways that meet land management considerations while meeting the conservation needs of the whitebark pine, as explained further below. The provisions of this rule are one of many tools that the Service would use to promote the conservation of the whitebark pine. This proposed 4(d) rule would apply only if and when the Service makes final the listing of the whitebark pine as a threatened species.

Provisions of the Proposed 4(d) Rule

This proposed 4(d) rule would provide for the conservation of whitebark pine by prohibiting the following activities (except in the case of the exceptions listed below), unless otherwise authorized or permitted:

- Import or export of the species;
- Delivery, receipt, transport, or shipment of the species in interstate or foreign commerce in the course of commercial activity;
- Sale or offer for sale of the species in interstate or foreign commerce;
- Removal and reduction to possession of the species from areas under Federal jurisdiction;
- Malicious damage or destruction of the species on any area under Federal jurisdiction; or
- Removal, cutting, digging up, or damage or destruction of the species on any area under Federal jurisdiction in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law.

These prohibitions and the exceptions below would apply to whitebark pine trees and any tree parts, such as cones, tree cores, etc.

The following activities would be excepted from the prohibitions identified above:

- Activities authorized by a permit under 50 CFR 17.72; and
- Forest management, restoration, or research-related activities conducted or authorized by the Federal agency with jurisdiction over the land where the activities occur.
- Removal, cutting, digging up, or damage or destruction of the species on areas not under Federal jurisdiction by any qualified employee or agent of the Service or State conservation agency which is a party to a Cooperative Agreement with the Service in accordance with section 6(c) of the Act, who is designated by that agency for such purposes, when acting in the course of official duties.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened plants under certain circumstances. Regulations governing permits are codified at 50 CFR 17.72. With regard to threatened plants, a permit may be issued for the following purposes: Scientific purposes, to enhance propagation or survival, for economic hardship, for botanical or

horticultural exhibition, for educational purposes, or for other purposes consistent with the purposes of the Act. Additional statutory exemptions from the prohibitions are found in sections 9 and 10 of the Act.

Broadly, the forest management, restoration, or research-related activities referred to above may include, but are not limited, to silviculture practices and forest management activities that address fuels management, insect and disease impacts, and wildlife habitat management (*e.g.,* cone collections, planting seedlings or sowing seeds, mechanical cuttings as a restoration tool in stands experiencing advancing succession, full or partial suppression of wildfires in whitebark pine communities, allowing wildfires to burn, survey and monitoring of tree health status), as well as other forest management, restoration, or research-related activities. We purposefully do not specify precisely when, where, or how these activities must be conducted because they are not a threat to whitebark pine in any form, and they may vary in how they are conducted across the species' wide range. This proposed 4(d) rule would enhance the conservation of whitebark pine by prohibiting activities that would be detrimental to the species, while allowing the forest management, restoration, and research-related activities that are necessary to conserve whitebark pine by maintaining and restoring forest health on the Federal lands that encompass the vast majority of the species' habitat within the United States.

The Service recognizes the special and unique relationship with our state natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist the Services in implementing all aspects of the Act. In this regard, section 6 of the Act provides that the Services shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve the whitebark pine that may result in otherwise prohibited activities without additional authorization.

We note that the prohibitions related to removing and reducing to possession; maliciously damaging and destroying; or removing, cutting, digging up, or destroying the species in this proposed 4(d) rule only apply to areas under Federal jurisdiction. Therefore, the exceptions to those prohibitions also only apply to areas under Federal jurisdiction. However, we still encourage forest management, restoration, and research-related activities on areas outside of Federal jurisdiction such as State, private, and Tribal lands within the United States or any lands within Canada. The proposed 4(d) rule only addresses Federal Endangered Species Act requirements, and would not change any prohibitions provided for by State law. Additionally, nothing in this proposed 4(d) rule would change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of whitebark pine. However, the consultation process may be further streamlined through programmatic consultations between Federal agencies and the Service for these activities. This proposed 4(d) rule would be finalized only after consideration of public comments and only if and when the Service makes final the listing of whitebark pine as threatened.

Necessary and Advisable Finding

The Service has determined that a 4(d) rule is appropriate for the whitebark pine. The proposed 4(d) rule would provide for the conservation of the species by use of protective regulations, as described here. Within the United States, the vast majority of the species' range (approximately 88 percent) is located on Federal lands. Given the reductions in resiliency that have already occurred to varying degrees across the range (Service 2018, pp. 56–82), we are proposing to apply the prohibitions of section 9(a)(2) of the Act to the whitebark pine by making the following activities unlawful:

- Import or export of the species;
- Delivery, receipt, transport, or shipment of the species in interstate or foreign commerce in the course of commercial activity;
- Sale or offer for sale of the species in interstate or foreign commerce;
- Removal and reduction to possession of the species from areas under Federal jurisdiction;
- Malicious damage or destruction of the species on any area under Federal jurisdiction; or
- Removal, cutting, digging up, or damage or destruction of the species on any area under Federal jurisdiction in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law.

However, we are also proposing to apply two broad exceptions to those prohibitions to allow authorization under 50 CFR 17.72, and to allow Federal land management agencies to continue managing the forest ecosystems where the whitebark pine occurs and to continue conducting restoration and research activities that benefit the species. The Service has concluded that the whitebark pine is likely to become endangered within the foreseeable future primarily due to the continued increase in white pine blister rust infection and associated mortality, synergistic and cumulative interactions between white pine blister rust and other stressors, and the resulting loss of seed source. This fungal disease is not human-spread or influenced by human activity, and few restoration methods are currently available to restore whitebark pine in areas affected by the disease. The whitebark pine is not commercially harvested, and while some human activities could potentially affect individual trees or local areas, we found no threats at the species level resulting from human activities, such as development or forest management activities. In fact, forest management activities are important to maintaining the health and resiliency of forest ecosystems that include whitebark pine.

As described in the SSA report (Service 2018, Appendix A), most current whitebark pine management and research focuses on producing trees with inherited (genetic) resistance to white pine blister rust, as well as implementing mechanical treatments and prescribed fire as conservation tools. As part of this process, cones may be collected from trees identified as apparently resistant to white pine blister rust, or ''plus'' trees. Additional current areas of research involve investigating natural regeneration and silvicultural treatments, such as appropriate site selection (*i.e.,* identifying areas where restoration will be most effective) and preparation, pruning, and thinning in order to protect high-value genetic resources, increase reproduction, reduce white pine blister rust damage, and increase stand volume (Zeglen *et al.* 2010, p. 361).

Conservation measures for whitebark pine can generally be categorized as

either protection (of existing healthy trees and stands) or restoration (of damaged, unhealthy, or extirpated trees and stands). Inventory, monitoring, and mapping of whitebark pine stands are critical for assessing the current status and implementing strategic conservation strategies. The precise nature of management, restoration, and research activities that are conducted may vary widely across the broad range of whitebark pine, as management of this species falls under numerous jurisdictions that encompass a spectrum of local and regional ecological, climatic, and management conditions and needs.

As no forest management, restoration, or research-related activities pose any threat to the whitebark pine in any form, we purposefully do not specify in detail what types of these activities are included in this exception, or how, when, or where they must be conducted, as long as they are conducted or authorized by the Federal agency with jurisdiction over the land where the activities occur. Therefore, this proposed 4(d) rule would allow the continuation of all such forest management, restoration, and research-related activities conducted by or authorized by relevant Federal land management agencies, as these activities pose no threat to the whitebark pine and are crucial to the species' conservation into the future, while allowing for flexibility to accommodate specific physical conditions, resource needs, and constraints across the species' vast range.

For the reasons discussed above, we find that this rule under section 4(d) of the Act is necessary and advisable to provide for the conservation of the whitebark pine. We ask the public, particularly Federal and State agencies and other interested stakeholders that may be affected by the proposed 4(d) rule, to provide comments and suggestions regarding additional guidance and methods that the Service could provide or use, respectively, to streamline the implementation of this proposed 4(d) rule (see Information Requested, above).

III. Critical Habitat Designation

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features that occur in specific areas, we focus on the specific features that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. When designating critical habitat, the Secretary will first evaluate areas occupied by the species. The Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species. In addition, for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those physical or biological features essential to the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information

Standards under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species to the maximum extent prudent and determinable. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

As explained below, we conclude that the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the whitebark pine, and therefore designating critical habitat is not prudent for the species.

Our analysis of the species' status found that the primary stressor driving the status of whitebark pine is disease (white pine blister rust, Factor C). White pine blister rust also interacts with other stressors, including predation by mountain pine beetles (Factor C), altered fire regimes (Factor E) and climate change (Factor E). While wildfires could in some cases be considered a negative impact on habitat as well as on individuals, wildfires may also have positive impacts on whitebark pine depending on severity and extent (*e.g.,* they may create spaces for seed-caching and eliminate competition from shade-tolerant species) (Keane and Parsons 2010, p. 57; Service 2018, pp. 31–34). In addition, we do not consider altered fire regimes, climate change, or the mountain pine beetle to be the main drivers of the status of the species.

Furthermore, habitat is not limiting for whitebark pine, which is widely distributed over a range of 32,616,422 ha (80,596,935 ac) (Service 2018, pp. 13–18). Our analysis evaluated the needs of whitebark pine at the individual, population, and species level. These needs include open space on the forest floor, and limited shading for all life stages of whitebark pine (Service 2018, pp. 21–27). In addition, populations need to maintain a sufficient density of reproductive adults for pollen dispersal and pollen clouds to facilitate masting, and to attract Clark's nutcrackers (Service 2018, pp. 27–28). These needs may be met in a variety of habitat types, as long as there are Clark's nutcrackers and limited competition. In fact, the habitat needs of whitebark pine are flexible and not specific, as evidenced by the fact that the species is extremely widespread, occupying a wide range of elevations, slopes, forest community types, latitudes, and climates across its 32,616,422-ha (80,596,935-ac) range (Service 2018, pp. 13–18). In other words, habitat for whitebark pine is plentiful, and is not a limiting factor determining the distribution of the species. Therefore, we do not consider the present or threatened destruction, modification, or curtailment of a species' habitat or range to be a threat to the species.

Since we have determined that the present or threatened destruction, modification, or curtailment of the species' habitat or range is not a threat to the whitebark pine, in accordance with 50 CFR 424.12(a)(1), we determine that designation of critical habitat is not prudent for the whitebark pine.

IV. Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes. We solicited information from Tribes within the range of whitebark pine to inform the development of our SSA, and

notified Tribes of our upcoming proposed listing determination. We also provided these Tribes the opportunity to review a draft of the SSA report and provide input prior to making our proposed determination on the status of the whitebark pine. We will continue to coordinate with affected Tribes throughout the listing process as appropriate.

References Cited

A complete list of references cited in this proposed rule is available on the internet at *http://www.regulations.gov* and upon request from the Wyoming Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Service's Mountain Prairie Regional Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

V. Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.12(h), add an entry for ''*Pinus albicaulis*'' to the List of Endangered and Threatened Plants in alphabetical order under CONIFERS to read as set forth below:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Scientific name	Common name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
Conifers				
*	*	*	*	*
Pinus albicaulis	Whitebark pine	Wherever found	T	[**Federal Register** citation when published as a final rule]; 50 CFR 17.74(a).[4d]
*	*	*	*	*

■ 3. Add § 17.74 to read as set forth below:

§ 17.74 Special rules—conifers and cycads.

(a) *Pinus albicaulis* (whitebark pine).

(1) The following prohibitions that apply to endangered plants also apply to the whitebark pine except as provided under paragraph (a)(2) of this section:

(i) Import or export, as set forth at § 17.61(b) for endangered plants.

(ii) Removal and reduction to possession of the species from areas under Federal jurisdiction; malicious damage or destruction of the species on any such area; or removal, cutting, digging up, or damage or destruction of the species on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law.

(iii) Interstate or foreign commerce in the course of commercial activity, as set forth at § 17.61(d) for endangered plants.

(iv) Sale or offer for sale, as set forth at § 17.61(e) for endangered plants.

(v) Attempt to commit, solicit another to commit, or cause to be committed, any of the acts described in paragraphs (a)(1)(i) through (iv).

(2) *Exceptions from prohibitions.* In regard to the whitebark pine, you may:

(i) Conduct activities as authorized by a permit under § 17.72.

(ii) Conduct forest management, restoration, or research-related activities conducted or authorized by the Federal agency with jurisdiction over the land where the activities occur.

(iii) Remove, cut, dig up, damage or destroy on areas under Federal jurisdiction by any qualified employee or agent of the Service or State conservation agency which is a party to a Cooperative Agreement with the Service in accordance with section 6(c) of the Act, who is designated by that agency for such purposes, when acting in the course of official duties.

(b) [Reserved]

Aurelia Skipwith,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2020–25331 Filed 12–1–20; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register

Vol. 85, No. 232

Wednesday, December 2, 2020

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0054]

Petition To Manufacture Foot-and-Mouth Disease Vaccine in the United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of petition and request for information; reopening of comment period.

SUMMARY: We are reopening the comment period for our notice of receipt of a petition from Zoetis, Inc. requesting approval for the manufacture within the continental United States of a vaccine derived from a leaderless strain of the foot-and-mouth disease (FMD) virus. Although introduction of live FMD virus into the United States is prohibited by law, the petition states that this leaderless strain should not be considered live FMD virus as it is non-infectious, non-transmissible, and incapable of causing FMD. We are taking this action in order to provide commenters with additional scientific information supporting our determination that the leaderless virus strain from which Zoetis, Inc. intends to produce FMD vaccine in the United States poses no risk of causing FMD infection in animals. This action gives interested persons the opportunity to review the additional information and submit comments.

DATES: The comment period for the notice published on July 14, 2020 (85 FR 42346–42347) is reopened. We will consider all comments that we receive on or before January 4, 2021.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0054.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0054, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0054* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading Room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Byron Rippke, Director, Center for Veterinary Biologics, APHIS, Veterinary Services, Diagnostics and Biologics, 1920 Dayton Ave., Ames, IA 50010; (515) 337–6101; *Byron.e.rippke@usda.gov.*

SUPPLEMENTARY INFORMATION: On July 14, 2020, we published in the **Federal Register** (85 FR 42346–42347, Docket No. APHIS–2020–0054) a notice and request for information [1] on a petition submitted by Zoetis, Inc. (Zoetis), a U.S. vaccine manufacturer, seeking approval from the Animal and Plant Health Inspection Service (APHIS) to manufacture within the continental United States a vaccine produced using a leaderless strain [2] of the foot-and-mouth disease (FMD) virus. A leaderless virus lacks part of the genetic code (the leader) critical for determining virulence in a host. Responses to this request for information will help us determine whether to authorize Zoetis to manufacture the vaccine in the United States for commercial distribution.

In the notice, we invited commenters to respond to questions about the risks of manufacturing an FMD vaccine in the United States and what safeguards might be necessary to address risk. We also asked commenters whether the leaderless strain of the virus intended for manufacture of a vaccine should be considered as a live FMD virus based on the Zoetis petition and information we supplied in the notice. This question is important in determining whether the prohibition in 21 U.S.C. 113a on introducing live FMD virus into the United States is applicable to a leaderless virus strain shown to be incapable of causing FMD infection in animals.

We solicited comments concerning our proposal for 60 days ending September 14, 2020. We received a total of 140 comments. While many commenters agreed that the Zoetis leaderless virus poses no FMD risk to U.S. livestock, several others raised safety concerns about using it to manufacture FMD vaccine in the United States. They stated that the notice and petition did not provide enough data to support a determination that the leaderless virus is not a live virus and that it poses no risk of causing FMD infection in animals. To address these concerns, we are providing additional data in this notice supporting the safety of the leaderless FMD virus and its use in manufacturing FMD vaccine and are reopening the comment period for 30 days.

Risk Assessment Summary

In 2017, Zoetis requested from the U.S. Department of Agriculture (USDA) a select agent exclusion for a leaderless strain of FMD virus intended to be used as a platform for producing FMD vaccine. In accordance with the regulations in 9 CFR part 122, USDA issued a permit allowing Zoetis to bring attenuated live FMD virus into the mainland United States for possible vaccine development. Before issuing the permit, USDA reviewed multiple documents and studies related to the request. The review encompassed synthetic virus production, virulence and safety, seroconversion, and concerns related to diagnostic differentiation of vaccinated and naturally infected animals. We concluded from these reviews that the Zoetis leaderless virus is incapable of infecting animals with FMD, and that vaccines produced using the leaderless virus as a platform are safe and efficacious in cattle and swine. Further details of our review findings are included in a risk assessment summary available via the link in footnote 1.

[1] To view the notice, the supporting document, and the comments we have received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0054.*

[2] Referred to in the Zoetis petition as FMD–LL3B3D A24 Cruzeiro vaccine platform virus.

In addition to the risk assessment summary, we wish to provide the following information regarding our evaluation.

Development and Safety of the FMD–LL3B3D Leaderless FMD Virus

The FMD–LL3B3D leaderless vaccine platform virus was created by deleting the leader (L) and one of three 3B genetic sequences of the FMD virus (L is a part of the virus that determines virulence), resulting in an attenuated virus that is innocuous for cattle and pigs but capable of growing in cell culture.[3] As a result, if the FMD–LL3B3D leaderless virus were to escape a manufacturing facility, it would be incapable of causing FMD in any animals exposed to it, nor could such animals spread the virus to other animals. In contrast, the risk of escape from facilities using traditionally virulent FMD viruses to manufacture vaccine is why many countries restrict FMD vaccine production to only local endemic strains. The deletion of L and the relevant 3B genetic sequence was therefore a key consideration in our evaluation.

Of similar importance was our review of available data regarding virulence of FMD–LL3B3D vaccines. Several FMD–LL3B3D vaccine viruses have been derived *in vitro* and characterized for their virulence in cattle and pigs. The cumulative data have shown that these FMD–LL3B3D marker viruses are highly attenuated in their natural hosts. Safety studies involving direct inoculation of live FMD–LL3B3D virus in cattle and pigs (see table 1) showed a high restriction of the novel vaccine virus to replicate and resulted in no clinical disease or transmission.[4]

TABLE 1—LIVE INNOCUITY STUDIES USING A VARIETY OF FMDLL3B3D VACCINE STRAINS IN CATTLE AND SWINE [1]

Construct	Inoculation route	Number of animals	Results
Cattle:			
FMD–LL3B3D–A24 Cruzeiro	Intralingual (7×10^6)	2	• No clinical disease.
FMD–LL3B3D–A24 Cruzeiro	Aerosol (1×10^6 to 3×10^6)	3	• No viral shedding.
FMD–LL3B3D–A24 Cruzeiro	Aerosol and Contact/(1×10^6)	9	• No fever spikes.
			• No contact transmission.
			• Very limited if any immune response.
Swine:			
FMD–LL3B3D–A24 Cruzeiro	Heelbulb and Contact (1×10^5)	4	• No clinical disease.
FMD–LL3B3D–Asia1 Shamir	Heelbulb and Contact (1×10^6)	5	• No viral shedding.
FMD–LL3B3D–A Turkey 06	Heelbulb and Contact (1×10^6)	5	• No fever spikes.
FMD–LL3B3D–O1 Campos	Heelbulb and Contact (1×10^6)	4	• No contact transmission.
FMD–LL3B3D–A Argentina	Heelbulb and Contact (2×10^6)	4	• Very limited if any immune response.
FMD–LL3B3D–C3 Indaial	Heelbulb and Contact (2.8×10^6)	4	

[1] Data prepared by Foreign Animal Disease Research Unit, USDA/ARS, Plum Island Animal Disease Center.

We are therefore reopening the comment period on Docket No. APHIS–2020–0054 for an additional 30 days. This action will allow interested persons to prepare and submit comments on the additional information we provided. We will also consider all comments received between September 14, 2020, and the date of this notice.

Authority: 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 25th day of November 2020.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020–26560 Filed 12–1–20; 8:45 am]

BILLING CODE 3410–34–P

[3] See the following studies for leaderless FMD virus safety data: Uddowla S., et al. A Safe Foot-and-Mouth Disease Vaccine Platform with Two Negative Markers for Differentiating Infected from Vaccinated Animals. *Journal of Virology* Oct 2012, 86(21) 11675–11685: DOI: 10.1128/JVI.01254–12; Eschbaumer M., et al. Foot-and-mouth disease virus lacking the leader 2 protein and containing two negative DIVA markers 3 (FMDV LL3B3D A24) is fully attenuated in pigs. *Pathogens.* (2020) 17:1–8: DOI: 10.3390/pathogens9020129; Hardham, John M., et al., Novel Foot-and-Mouth Disease Vaccine Platform: Formulations for Safe and DIVA-Compatible FMD Vaccines with Improved Potency. *Frontiers in Veterinary Science,* 25 September 2020; *https://doi.org/10.3389/fvets.2020.554305.*

[4] In a 2018 meeting report drafted by the Global Foot-and-Moth Disease Research Alliance that reviewed FMD vaccine platforms, the FMDLL3B3D platform received the highest score. Global Foot-and-Mouth Disease Research Alliance, Gap Analysis Report. December 2018: *https://go.usa.gov/xdrKh.*

DEPARTMENT OF AGRICULTURE

Forest Service

Medicine Bow-Routt National Forests and Thunder Basin National Grassland; Wyoming; 2020 Thunder Basin National Grassland Plan Amendment

AGENCY: Forest Service, USDA.

ACTION: Notice of Grassland Plan amendment approval.

SUMMARY: Russell M. Bacon, Forest Supervisor for the Medicine Bow-Routt National Forests and Thunder Basin National Grassland, Rocky Mountain Region, signed the final Record of Decision (ROD) for the 2020 Thunder Basin National Grassland Land and Resource Management Plan Amendment (Grassland Plan amendment). The Final ROD documents the rationale for approving the Grassland Plan amendment and is consistent with the Reviewing Officer's response to objections and instructions.

DATES: The effective date of the Grassland Plan amendment is 30 days after publication of notice of Grassland Plan amendment approval in the newspaper of record, the *Laramie Boomerang.*

ADDRESSES: To view the final ROD, final environmental impact statement (FEIS), FEIS errata, objection responses, and other related documents, visit the 2020 Thunder Basin National Grassland Plan Amendment website at *https://www.fs.usda.gov/project/?project=55479.*

FOR FURTHER INFORMATION CONTACT: Monique Nelson, plan amendment team leader, by email at *monique.nelson@usda.gov* or by telephone at 307–275–0956.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339

between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Grassland Plan amendment addresses management of black-tailed prairie dog colonies on National Forest System land within the administrative boundary of the Thunder Basin National Grassland. New and amended plan components remove a 56,000-acre ''Black-footed Ferret Reintroduction Habitat'' management area and designate a new 42,000-acre ''Short-Stature Vegetation Emphasis'' management area; set an objective of 10,000 acres of prairie dog colonies for conservation of wildlife habitat; establish prairie dog management zones along boundaries between National Forest System land and private or state properties; allow broader application of tools for prairie dog colony control; and increase emphasis on management of sylvatic plague. The Grassland Plan amendment was informed by the best available scientific information, current laws and regulations, and collaborative relationships with cooperating agencies and stakeholder groups.

Cooperating Agencies

U.S. Fish and Wildlife Service, Wyoming Field Office; Natural Resources Conservation Service, Wyoming State Office; Wyoming Department of Agriculture; Wyoming Game and Fish Department; Wyoming State Office of Lands and Investments; Wyoming Weed and Pest Council; Campbell County, WY; Converse County, WY; Crook County, WY; Niobrara County, WY; Weston County, WY.

Responsible Official

Russell M. Bacon, Forest Supervisor, Medicine Bow Routt National Forests and Thunder Basin National Grassland.

Christine Dawe,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2020–26563 Filed 12–1–20; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Delaware Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that planning meetings of the Delaware Advisory Committee to the Commission will convene by conference call, on the following Wednesdays at 1:00 p.m. (ET): November 4 and December 2, 2020 and January 6 and February 3, 2021. The purpose of the meetings is for project planning and possible selection of project topic and project proposal.

DATES: Wednesdays at 1:00 p.m. (ET), November 4 and December 2, 2020 and January 6 and February 3, 2021.

ADDRESSES: *Public Call-In Information:* Conference call number: 1–800–367–2403 and conference call ID: 4195799.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call number: 1–800–367–2403 and conference call ID: 4195799. Please be advised that before placing them into the conference calls, the conference call operator may ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number herein.

Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Federal Relay Service operator with the conference call-in numbers: 1–800–822–2024 and conference call ID: 4195799.

Members of the public are invited to make brief statements during the Public Comment section of each meeting or to submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting via email to Ivy Davis at *ero@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing, as they become available, at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above email address.

Agenda

Wednesdays at 1:00 p.m. (ET): Nov. 4 and Dec. 2, 2020 and Jan. 6 and Feb. 3, 2021

I. Welcome and Roll Call

II. Project Planning

III. Other Business

IV. Next Planning Meeting

V. Public Comments

VI. Adjourn

Dated: November 25, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–26553 Filed 12–1–20; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–174–2020]

Approval of Subzone Expansion; ASML US, LLC; Wilton, Connecticut

On October 5, 2020, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Bridgeport Port Authority, grantee of FTZ 76, requesting an expansion of Subzone 76A subject to the existing activation limit of FTZ 76, on behalf of ASML US, LLC, in Wilton, Connecticut.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (85 FR 63505, October 8, 2020). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to expand Subzone 76A was approved on November 25, 2020, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 76's 476-acre activation limit.

Dated: November 25, 2020.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2020–26578 Filed 12–1–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 201124–0316]

RIN 0694–XC068

Notice of Request for Public Comments on Condition of the Public Health Industrial Base and Recommend Policies and Actions To Strengthen the Public Health Industrial Base To Ensure Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States

AGENCY: Bureau of Industry and Security, Office of Technology Evaluation, U.S. Department of Commerce.

ACTION: Notice of request for public comments.

SUMMARY: On August 6, 2020, President Trump issued an Executive order, *Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States.* Among other directives, the E.O. directed that, by February 2, 2021, the Secretary of Commerce shall submit a report to the Director of the Office of Management and Budget, the Assistant to the President for National Security Affairs, the Director of the National Economic Council, and the Director of the Office of Trade and Manufacturing Policy, describing any change in the status of the Public Health Industrial Base (PHIB) and recommending initiatives to strengthen the PHIB. This notice requests comments from the public to assist the Department of Commerce (referred to henceforth as ''Commerce'') in preparing this report on the condition of the PHIB and recommending policies and actions to strengthen the PHIB.

DATES: The due date for filing comments is December 23, 2020.

ADDRESSES: *Submissions:* All written comments on the notice must be addressed to PHIB Study and filed through the Federal eRulemaking Portal: *http://www.regulations.gov.* To submit comments via *http://www.regulations.gov,* enter docket number BIS–2020–0034 on the home page and click ''search.'' The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice and click on the link entitled ''Comment Now!'' (For further information on using *http://www.regulations.gov,* please consult the resources provided on the website by clicking on ''How to Use This Site.'')

FOR FURTHER INFORMATION CONTACT: Jason Bolton at 202–482–5936 or via email *Jason.Bolton@bis.doc.gov; PHIBstudy@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

On August 6, 2020, President Trump issued Executive Order 13944, *Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States* (E.O. 13944). Section 1 of E.O. 13944 stated that the United States must protect U.S. citizens, critical infrastructure, military forces, and the economy against outbreaks of emerging infectious diseases as well as chemical, biological, radiological, and nuclear (CBRN) threats. To achieve this, the United States must have a strong Public Health Industrial Base (PHIB) with resilient domestic supply chains for the Essential Medicines, Medical Countermeasures, and Critical Inputs deemed necessary for the United States. As defined in E.O. 13944, ''Essential Medicines'' are those Essential Medicines deemed necessary for the United States pursuant to section 3(c) of E.O. 13944; ''Medical Countermeasures'' means items that meet the definition of ''qualified countermeasure'' in section 247d–6a(a)(2)(A) of title 42, United States Code; ''qualified pandemic or epidemic product'' in section 247d–6d(i)(7) of title 42, United States Code; ''security countermeasure'' in section 247d–6b(c)(1)(B) of title 42, United States Code; or personal protective equipment described in part 1910 of title 29, Code of Federal Regulations. Section 7 of E.O. 13944 contains the definitions of other terms that are applicable to this notice (*e.g.,* ''Active Pharmaceutical Ingredient,'' ''Advanced Manufacturing,'' ''API Starting Material,'' ''Critical Inputs,'' ''Finished Device,'' ''Finished Drug Product,'' ''Healthcare and Public Health Sector,'' and ''Qualifying Countries''). The definition of ''produced in the United States'' used in this notice is consistent with the definition of ''produced in the United States'' as used in Section 25.1 of the Federal Acquisition Regulation (FAR) *Buy American Act-Supplies* and in the FAR Clause 52.225–1.

Section 1 of E.O. 13944 directs that domestic supply chains must be capable of meeting national security requirements for responding to threats arising from CBRN threats and public health emergencies, including emerging infectious diseases such as COVID–19. The E.O. further states that it is critical that the United States reduce its dependence on foreign manufacturers for Essential Medicines, Medical Countermeasures, and Critical Inputs to ensure sufficient and reliable long-term domestic production of these products, minimize potential shortages, and mobilize our Nation's PHIB to respond to these threats. The E.O. directed that the policy of the United States is to accelerate the development of cost-effective and efficient domestic production of Essential Medicines and Medical Countermeasures and to have adequate redundancy built into the domestic supply chain; ensure long-term demand for these items, and critical inputs that are produced in the United States; create, maintain, and maximize domestic production capabilities for these items that are essential to protect public safety and human health and to provide for the national defense; and combat the trafficking of these items, and critical inputs over e-commerce platforms and from third party online sellers involved in the government procurement process.

In E.O. 13994, the President directed the heads of Executive Branch agencies, including the Secretary of Commerce, to fulfill the stated policy objectives of the order. Under section 6, paragraph (b) (Reporting) of the E.O., the Secretary is directed, by February 2, 2021 (within 180 days of the date of the August 6 order), to submit a report to the Director of the Office of Management and Budget (OMB), the Assistant to the President for National Security Affairs, the Director of the National Economic Council, and the Director of the Office of Trade and Manufacturing Policy, describing any change in the status of the Public Health Industrial Base and recommending initiatives to strengthen the Public Health Industrial Base.

This notice requests comments from the public to assist Commerce in preparing this report on the condition of the PHIB (''change in the status'') and recommending policies and actions (''initiatives'') to strengthen the PHIB.

As stated in section 6, paragraph (c) of E.O. 13944, to the maximum extent permitted by law, and with the redaction of any information protected by law from disclosure, Commerce's report shall be published in the **Federal Register** and on the agency's official website.

Definition of Public Health Industrial Base (PHIB)

As defined in E.O. 13944, ''PHIB'' means the facilities and associated workforces within the United States, including research and development facilities, which help produce Essential Medicines, Medical Countermeasures, and Critical Inputs for the Healthcare

and Public Health Sector. The PHIB includes all entities domestically manufacturing or producing medical products, including medical devices, medical equipment, medical countermeasures, and medications, pharmaceutical products, and other products designed to improve patient outcomes. This includes the manufacturing of components and materials that are essential to create end-item medical products, as well as ancillary supplies and disposable consumable products.

For medical devices and medical equipment, the PHIB includes all components that, if replaced by an equivalent alternative component, would require an amendment to the final product's 510(k) certification. For medications and pharmaceutical products, it includes drug finishing (*i.e.,* fill-finish, tableting, or capsule formulation), as well as the active pharmaceutical ingredients (API) and the key starting materials that are used to make the API. For blood products and medical products derived from animals (such as porcine and bovine heparin), the PHIB includes all aspects of the extraction, processing and formulation supply chain. For vaccines and biologics, it includes research and development, as well as the production of all components of the end product without which the end product would be ineffective for its intended purpose.

The PHIB also includes the labor force necessary to conduct the manufacturing and supply chain operations described above. It does not include the ability of distributors to source medical products from foreign sources to distribute within the U.S. healthcare system.

Written Comments

Interested parties are invited to submit written comments, data, analyses, or information pertinent to the task of preparing this Commerce report pursuant to E.O. 13994 to the Department's Office of Technology Evaluation no later than December 23, 2020.

The Department is particularly interested in comments and information directed to the policy objectives listed in E.O. 13944 as they affect the U.S. PHIB including, but not limited to, the following:

(i) What is the condition of the current U.S. PHIB? Commenters in responding to this question are encouraged to reference their position in the PHIB (*e.g.,* research and development facility, manufacturer, distributor, or consumer).

(ii) What policies and actions should the U.S. Government take to strengthen the PHIB in the United States?

(iii) What aspects or parts of the PHIB are most vulnerable during outbreaks of emerging infectious diseases?

a. How likely might such an event be, how much of an impact might it have in manufacturing operations, and what mitigation measures might be most effective in offsetting these impacts?

b. In responding to this question, commenters are encouraged to include any lessons learned from responding to COVID–19 or other historic pandemics, and the ramping up of U.S. capacity in various areas that did or did not occur to meet these challenges.

(iv) What aspects or parts of the PHIB are most vulnerable to chemical, biological, radiological, and nuclear (CBRN) events?

a. How likely might such an event be; how much might it impact manufacturing operations; and what mitigation measures might be most effective in offsetting these impacts.

b. In responding to this question, commenters are encouraged to include any lessons learned from responding to previous CBRN threats and the ramping up of U.S. capacity in various areas that did or did not occur to meet these challenges.

(v) For the Essential Medicines, Medical Countermeasures, and Critical Inputs with which your organization is involved under the PHIB, for what percentage of these items are you dependent on foreign suppliers? In responding to this question, please address:

a. Whether or not there are foreign dependencies in any part of your supply chain for critical inputs (*e.g.,* active pharmaceutical ingredients (APIs)) or for finished products?

b. whether it would be possible to source these critical inputs and/or finished products from the United States, as well as how long you anticipate it would take to source these items from U.S. suppliers if your foreign supplier(s) was no longer available?

(vi) Are there any costs, regulatory or other factors that make it difficult or impossible to produce or source Essential Medicines, Medical Countermeasures, and/or Critical Inputs in the United States? In addressing this question, please also address:

a. Any concerns that you may have regarding sourcing or producing these items in the United States, in contrast to sourcing or producing them outside the United States.

b. does your organization have mechanisms to determine whether Essential Medicines, Medical Countermeasures, and Critical Inputs are produced in the United States? What, if any, are the limitations to those mechanisms? Commenters are encouraged to be as specific as possible in their comments regarding the particular issues that may exist. For example, an example of a regulatory provision accompanied by a specific example of how the provision hinders domestic production is more helpful to Commerce than a statement that the regulatory environment in the United States discourages domestic production.

c. how significant of a concern is ''pricing'' in being able to achieve maximum domestic production?

(vii) What is the U.S. Government doing or could do to foster private and public sector investment and innovation in the U.S. PHIB, including, for example, investments in upgrades to equipment, or the adoption of emerging technologies, and/or automation that would increase productivity and competitiveness. Should the U.S. Government do more to foster U.S. PHIB investment, particularly in automation and emerging technologies? If so, what policy actions should it undertake?

(viii) With respect to the U.S. PHIB, what are the challenges to investing in automation and other productivity-enhancing technologies in the United States as compared to moving operations abroad to lower-cost labor countries? Would increased investment in, or higher use of, more efficient and cost-effective automation and productivity enhancing technologies affect your decisions to source all or some of your Essential Medicines, Medical Countermeasures, and Critical Inputs in the United States?

(ix) Briefly assess whether the amount of federal funds spent on U.S. PHIB research and development (R&D) is adequate; if not, specify why spending should be increased or decreased. Which types of R&D projects, if adequately funded, would have the most impact on the competitiveness of the U.S. PHIB supply chain?

(x) Briefly assess U.S. Federal procurement policy with respect to the U.S. PHIB and how it encourages or discourages investment in the PHIB. How should U.S. Federal procurement policy to make the PHIB more productive and more internationally competitive, as well as to encourage investment in automation and other emerging technologies?

(xi) What are the workforce challenges to strengthening the U.S. PHIB, and what are best practices or suggestions for how U.S. industry can overcome these challenges? What have you done to address these challenges? How might

emerging technologies in the PHIB create new workforce training needs? Which skillsets will the job market most demand in the future?

(xii) How can the U.S. Government or the private sector help to accelerate the development of cost-effective and efficient domestic production of Essential Medicines and Medical Countermeasures and to have adequate redundancy built into the domestic supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs?

(xiii) What are the three most important things that can be done by the U.S. Government or the private sector to ensure long-term demand for the Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States?

(xiv) What are the three most important things that can be done by the U.S. Government or the private sector to create, maintain, and maximize domestic production capabilities for the Critical Inputs, Finished Drug Products, and Finished Devices that are essential to protect public safety and human health and to provide for the national defense?

(xv) How significant of a problem is trafficking of counterfeit Essential Medicines, Medical Countermeasures, and Critical Inputs over e-commerce platforms and from third party online vendors also involved in the U.S. Government procurement process? In responding to this question, commenters are encouraged to provide specific examples of how these practices may have undermined production in the United States, endangered U.S. citizens, or undermined the reliability of the U.S. supply chain.

(xvi) How great of a threat is cybercrime or malicious cyber activity to your organization and other organizations that you depend on as part of your supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs? In addressing this question, commenters are encouraged to provide specific examples of how cyber threats (*e.g.,* ransomware, distributed denial of service attacks (DDoS) and malware) have undermined production in the United States and the reliability of the U.S. supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs. How can the U.S. Government or the private sector strengthen the PHIB sector's ability to prevent, detect, and recover from malicious cyber activity? To what extent, if any, does dependence on foreign suppliers increase your organization's exposure to cybercrime or create additional burdens because of the complexities involved in dealing with different countries' laws on cyber issues?

(xvii) From your organization's perspective, how dependent is the U.S. supply chain on foreign suppliers for items for use in Personal Protective Equipment (PPE)? In addressing this question, please address whether there are specific factors that undermine U.S. competitiveness in this area and provide any recommendations that your organization may have for reducing foreign dependency and increasing U.S. competitiveness. In addressing this question, specify whether your organization produces, sells or uses PPE.

Requirements for Written Comments

The *http://www.regulations.gov* website allows users to provide comments by filling in a ''Type Comment'' field, or by attaching a document using an ''Upload File'' field. The Department prefers that comments be provided in an attached document. The Department prefers submissions in Microsoft Word (.doc files) or Adobe Acrobat (.pdf files). If the submission is in an application format other than Microsoft Word or Adobe Acrobat, please indicate the name of the application in the ''Type Comment'' field. Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter within the comments. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file, so that the submission consists of one file instead of multiple files. Comments will be placed in the docket and open to public inspection, unless a statement is filed justifying nondisclosure and referring to the specific legal authority claimed, and a non-confidential version of the submission is provided. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission. Comments may be viewed on *http://www.regulations.gov* by entering docket number BIS–2020–0034 in the search field on the home page.

All filers should name their files using the name of the person or entity submitting the comments. Communications from agencies of the United States Government will not be made available for public inspection.

Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission. Guidance on submitting business confidential information is as follows: Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, include a statement justifying nondisclosure and referring to the specific legal authority claimed with the submission, and provide a non-confidential version of the submission which will be placed in the public file on *http://www.regulations.gov.* For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC''. Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. The non-confidential version must be clearly marked ''PUBLIC''. The file name of the non-confidential version should begin with the character ''P''. The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments or rebuttal comments. If a public hearing is held in support of this investigation, a separate **Federal Register** notice will be published providing the date and information about the hearing.

The Bureau of Industry and Security does not maintain a separate public inspection facility. Requesters should first view the Bureau's web page, which can be found at *https://efoia.bis.doc.gov/* (see ''Electronic FOIA'' heading). If requesters cannot access the website, they may call 202–482–0795 for assistance. The records related to this assessment are made accessible in accordance with the regulations published in part 4 of title 15 of the Code of Federal Regulations (15 CFR 4.1 through 4.11).

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–26609 Filed 11–30–20; 4:15 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

Background

Every five years, pursuant to the Tariff Act of 1930, as amended (the Act), the Department of Commerce (Commerce) and the International Trade Commission automatically initiate and conduct reviews to determine whether revocation of a countervailing or antidumping duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

Upcoming Sunset Reviews for January 2021

Pursuant to section 751(c) of the Act, the following Sunset Reviews are scheduled for initiation in January 2021 and will appear in that month's *Notice of Initiation of Five-Year Sunset Reviews* (Sunset Review).

	Department contact
Antidumping Duty Proceedings	
Magnesia Carbon Bricks from China (A–570–954) (2nd Review)	Matthew Renkey; (202) 482–2312.
Magnesia Carbon Bricks from Mexico (A–201–837) (2nd Review)	Matthew Renkey; (202) 482–2312.
Countervailing Duty Proceedings	
Magnesia Carbon Bricks from China (C–570–955) (2nd Review)	Matthew Renkey; (202) 482–2312.

Suspended Investigations

No Sunset Review of suspended investigations is scheduled for initiation in January 2021.

Commerce's procedures for the conduct of Sunset Review are set forth in 19 CFR 351.218. The *Notice of Initiation of Five-Year (Sunset) Review* provides further information regarding what is required of all parties to participate in Sunset Review.

Pursuant to 19 CFR 351.103(c), Commerce will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact Commerce in writing within 10 days of the publication of the Notice of Initiation.

Please note that if Commerce receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue.

Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation. Note that Commerce has modified certain of its requirements for serving documents containing business proprietary information, until further notice.[1]

This notice is not required by statute but is published as a service to the international trading community.

Dated: November 24, 2020.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2020–26581 Filed 12–1–20; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (Commerce) conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 21 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will

not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete a Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

Opportunity to Request a Review: Not later than the last day of December 2020,[2] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in December for the following periods:

	Period to be reviewed
Antidumping Duty Proceedings	
BRAZIL: Carbon Steel Butt-Weld Pipe Fittings, A–351–602	12/1/19–11/30/20
CHILE: Certain Preserved Mushrooms, A–337–804	12/1/19–11/30/20
GERMANY: Non-Oriented Electrical Steel, A–428–843	12/1/19–11/30/20
INDIA: Carbazole Violet Pigment 23, A–533–838	12/1/19–11/30/20
INDIA: Certain Hot-Rolled Carbon Steel Flat Products, A–533–820	12/1/19–11/30/20
INDIA: Commodity Matchbooks, A–533–848	12/1/19–11/30/20
INDIA: Stainless Steel Wire Rod, A–533–808	12/1/19–11/30/20
INDONESIA: Certain Hot-Rolled Carbon Steel Flat Products, A–560–812	12/1/19–11/30/20
JAPAN: Prestressed Concrete Steel Wire Strand, A–588–068	12/1/19–11/30/20
JAPAN: Non-Oriented Electrical Steel, A–588–872	12/1/19–11/30/20
JAPAN: Welded Large Diameter Line Pipe, A–588–857	12/1/19–11/30/20
OMAN: Circular Welded Carbon-Quality Steel Pipe, A–523–812	12/1/19–11/30/20
PAKISTAN: Circular Welded Carbon-Quality Steel Pipe, A–535–903	12/1/19–11/30/20
REPUBLIC OF KOREA: Non-Oriented Electrical Steel, A–580–872	12/1/19–11/30/20
REPUBLIC OF KOREA: Welded Astm A–312 Stainless Steel Pipe, A–580–810	12/1/19–11/30/20
REPUBLIC OF KOREA: Welded Line Pipe, A–580–876	12/1/19–11/30/20
RUSSIA: Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products, A–821–809	12/1/19–11/30/20
SINGAPORE: Acetone, A–559–808	8/5/19–11/30/20
SOCIALIST REPUBLIC OF VIETNAM: Uncovered Innerspring Units, A–552–803	12/1/19–11/30/20
SOUTH AFRICA: Uncovered Innerspring Units, A–791–821	12/1/19–11/30/20
SPAIN: Acetone, A–469–819	8/5/19–11/30/20
SWEDEN: Non-Oriented Electrical Steel, A–401–809	12/1/19–11/30/20
TAIWAN: Carbon Steel Butt-Weld Pipe Fittings, A–583–605	12/1/19–11/30/20
TAIWAN: Non-Oriented Electrical Steel, A–583–851	12/1/19–11/30/20
TAIWAN: Steel Wire Garment Hangers, A–583–849	12/1/19–11/30/20
TAIWAN: Welded Astm A–312 Stainless Steel Pipe, A–583–815	12/1/19–11/30/20
THAILAND: Carbon and Alloy Steel Threaded Rod, A–549–840	8/7/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Aluminum Wire, A–570–095	6/5/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Carbazole Violet Pigment 23, A–570–892	12/1/19–11/30/20

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[2] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when Commerce is closed.

	Period to be reviewed
THE PEOPLE'S REPUBLIC OF CHINA: Cased Pencils, A–570–827	12/1/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, A–570–979	12/1/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Hand Trucks and Certain Parts Thereof, A–570–891	12/1/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Honey, A–570–863	12/1/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Malleable Cast Iron Pipe Fittings, A–570–881	12/1/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Mattresses, A–570–092	6/4/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Melamine, A–570–020	12/1/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Multilayered Wood Flooring, A–570–970	12/1/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Non-Oriented Electrical Steel, A–570–996	12/1/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Porcelain-On-Steel Cooking Ware, A–570–506	12/1/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Refillable Stainless Steel Kegs, A–570–093	12/13/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Silicomanganese, A–570–828	12/1/19–11/30/20
THE PEOPLE'S REPUBLIC OF CHINA: Vertical Metal File Cabinets, A–570–110	8/1/19–11/30/20
TURKEY: Welded Line Pipe, A–489–822	12/1/19–11/30/20
UNITED ARAB EMIRATES: Circular Welded Carbon-Quality Steel Pipe, A–520–807	12/1/19–11/30/20
Countervailing Duty Proceedings	
INDIA: Carbazole Violet Pigment 23, C–533–839	1/1/19–12/31/19
INDIA: Certain Hot-Rolled Carbon Steel Flat Products, C–533–821	1/1/19–12/31/19
INDIA: Commodity Matchbooks, C–533–849	1/1/19–12/31/19
INDONESIA: Certain Hot-Rolled Carbon Steel Flat Products, C–560–813	1/1/19–12/31/19
TAIWAN: Non-Oriented Electrical Steel, C–583–852	1/1/19–12/31/19
THAILAND: Certain Hot-Rolled Carbon Steel Flat Products, C–549–818	1/1/19–12/31/19
THE PEOPLE'S REPUBLIC OF CHINA: Aluminum Wire and Cable, C–570–096	4/8/19–12/31/19
THE PEOPLE'S REPUBLIC OF CHINA: Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, C–570–980	1/1/19–12/31/19
THE PEOPLE'S REPUBLIC OF CHINA: Melamine, C–570–021	1/1/19–12/31/19
THE PEOPLE'S REPUBLIC OF CHINA: Non-Oriented Electrical Steel, C–570–997	1/1/19–12/31/19
THE PEOPLE'S REPUBLIC OF CHINA: Multilayered Wood Flooring, C–570–971	1/1/19–12/31/19
THE PEOPLE'S REPUBLIC OF CHINA: Refillable Stainless Steel Kegs, C–570–094	12/13/19–12/31/19
THE PEOPLE'S REPUBLIC OF CHINA: Vertical Metal File Cabinets, C–570–111	8/1/19–12/31/19
TURKEY: Welded Line Pipe, C–489–823	1/1/19–12/31/19
Suspension Agreements	
MEXICO: Sugar, A–201–845	12/1/19–11/30/20
MEXICO: Sugar, C–201–846	1/1/19–12/31/19

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.[3]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an antidumping duty administrative reviews.[4] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[5] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate

[3] *See* the Enforcement and Compliance website at *https://legacy.trade.gov/enforcement/.*

[4] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[5] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an antidumping administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Enforcement and Compliance's ACCESS website at *https://access.trade.gov*.[6] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[7]

Commerce will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of December 2020. If Commerce does not receive, by the last day of December 2020, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: November 18, 2020.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2020–26580 Filed 12–1–20; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[7] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Rulings

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable December 2, 2020.

SUMMARY: The Department of Commerce (Commerce) hereby publishes a list of scope rulings and anti-circumvention determinations made during the period July 1, 2020, through September 30, 2020. We intend to publish future lists after the close of the next calendar quarter.

FOR FURTHER INFORMATION CONTACT: Marcia E. Short, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–1560.

SUPPLEMENTARY INFORMATION:

Background

Commerce regulations provide that the agency will publish in the **Federal Register** a list of scope rulings on a quarterly basis.[1] Our most recent notification of scope rulings was published on September 28, 2020.[2] This current notice covers all scope rulings and anti-circumvention determinations made by Enforcement and Compliance between July 1, 2020–September 30, 2020.

[1] *See* 19 CFR 351.225(o).

[2] *See Notice of Scope Rulings,* 85 FR 60762 (September 28, 2020).

Scope Rulings Made July 1, 2020 Through September 30, 2020

Republic of Korea (Korea)

A–580–836 and C–580–837: Certain Cut-to-Length Carbon-Quality Steel Plate Products From Korea

Requestor: Dongkuk Steel Mill Co., Ltd.; non-rectangular cross-section products (or, longitudinally-profiled 'LP' plates) produced, but not yet exported to the United States, and identified by the 3-letter prefixes in the 14-digit product codes FPD (differenced thickness plate), FPS (step plate), and FPT (tapered plate), are outside the scope of the antidumping duty (AD) and countervailing duty (CVD) orders, August 4, 2020.

People's Republic of China (China)

A–570–822: Certain Helical Spring Lock Washers From China

Requestor: MacLean Power, L.L.C. (MPS). Helical spring lock washers incorporated in MPS's pole line hardware are outside the scope of the order because pole line hardware imported by MPS are distinct assembled products for use in the attachment of cables and wires onto utility poles. March 19, 2019. This is a revision, based on litigation, to our previous scope ruling.[3]

A–570–967 and C–570–968: Aluminum Extrusions From China

Requestor: Schletter Inc. Eight models of grounding clamps, designed for securing solar panels to solar panel racking systems, are covered by the scope of the AD and CVD orders on aluminum extrusions from China because they consist of aluminum extrusion components that are attached to form subassemblies, and they lack the necessary components that would allow them to function as a finished solar panel mounting system; August 10, 2020.

Anti-Circumvention Determinations Made July 1, 2020, Through September 30, 2020

A–570–026 and C–570–027: Certain Corrosion-Resistant Steel Products (CORE) From China

Self-initiated: CORE completed in Costa Rica and the UAE from hot-rolled steel or cold-rolled steel substrate manufactured in China, and subsequently exported to the United States is circumventing the AD and CVD

[3] Our initial ruling was published in *Notice of Scope Rulings,* 84 FR 11742, 11743 (March 28, 2019). The Court of International Trade finalized its ruling on March 19, 2019.

orders on CORE from China. CORE produced in Guatemala is not circumventing the orders; July 6, 2020.

A–570–028: Hydrofluorocarbon Blends From f China

Commerce determined not to include hydrofluorocarbon (HFC) components from China (R–32, R–125, R–143a) imported into the United States for further processing into HFC blends within the scope of the AD order on HFC blends from China; August 13, 2020.

Notification to Interested Parties

Interested parties are invited to comment on the completeness of this list of completed scope inquiries and anti-circumvention determinations made during the period July 1, 2020, through September 30, 2020. Any comments should be submitted to the Deputy Assistant Secretary for AD/CVD Operations, Enforcement and Compliance, International Trade Administration, 1401 Constitution Avenue NW, APO/Dockets Unit, Room 18022, Washington, DC 20230.

This notice is published in accordance with 19 CFR 351.225(o).

Dated: November 25, 2020.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2020–26582 Filed 12–1–20; 8:45 am]

BILLING CODE 3510–DS–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Proposed Revised Collection, Comment Request: "Swap Data Recordkeeping and Reporting Requirements"

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is announcing an opportunity for public comment on the revision of an information collection by the agency. Under the Paperwork Reduction Act of 1995 (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each revised collection of information and to allow 60 days for public comment. The Commission recently adopted a final rule amending requirements for swap data recordkeeping and reporting. This notice solicits additional comments on certain estimated costs and burdens associated with the amended requirements.

DATES: Comments must be submitted on or before February 1, 2021.

ADDRESSES: You may submit comments, identified by ''Swap Data Recordkeeping and Reporting Requirements, OMB Control No. 3038–0096,'' by any of the following methods:

- The Agency's website, at *http://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Meghan Tente, Acting Deputy Director, Division of Market Oversight, Commodity Futures Trading Commission, (202) 418–5785, email: *mtente@cftc.gov,* and refer to OMB Control No. 3038–0096.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (''OMB'') for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed information collection including each proposed revision or extension of an existing information collection, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Title: Swap Data Recordkeeping and Reporting Requirements (OMB Control No. 3038–0096). This is a request for comment on a currently approved information collection.

Abstract: The collection of information is needed to ensure that the CFTC and other regulators have access to swap data as required by the Commodity Exchange Act, as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''). The Dodd-Frank Act directed the CFTC to adopt rules providing for the reporting of data relating to swaps.

On September 17, 2020, the Commission adopted a rulemaking amending its part 45 regulations.[1] In the release accompanying the final rule, the Commission included some estimated costs and burdens that were not included in the proposal and made corrections to some of its previous estimates. The Commission explains these cost and burden estimates below and invites comment on any new or revised estimates.

1. Amendments to Regulation 45.3

Amended § 45.3 creates costs for swap data repositories (''SDRs''), swap execution facilities (''SEFs''), designated contract markets (''DCMs''), and reporting counterparties to update systems for reporting required swap creation data reports. For the proposal, the Commission estimated SDRs, SEFs, DCMs, and reporting counterparties would incur a one-time initial burden of 10 hours per entity to modify their systems to adopt the changes, for a total estimated hours burden of 17,320 hours. The cost per entity was estimated to be $722.30 for a total cost across entities of $1,251,024. The Commission additionally estimated 5 hours per entity annually to perform any needed maintenance or adjustments to reporting systems, at a cost of $361.15 per entity and $625,512 across entities.[2] The Commission re-evaluated the analysis in the final rule and instead used a wage estimate of between $48 and $101[3] per

[1] The Commission proposed the amendments to Part 45 in February 2020. Swap Data Recordkeeping and Reporting Requirements, 75 FR 21578 (Apr. 17, 2020) (the ''Proposal''). The final rule was published in the **Federal Register** on November 25, 2020.

[2] The PRA section of the Proposal included one-time and ongoing burden hour estimates for entities to modify their systems. The associated cost estimates referenced above were included in the related Supporting Statement filed with OMB for the Proposal.

[3] Hourly wage rates for this aspect came from the Software Developers and Programmers category of the May 2019 National Occupational Employment and Wage Estimates Report produced by the U.S. Bureau of Labor Statistics, available at *https://www.bls.gov/oes/current/oes_nat.htm.* The 25th percentile was used for the low range and the 90th percentile was used for the upper range ($36.89 and $78.06, respectively). Each number was multiplied by an adjustment factor of 1.3 for overhead and

Continued

hour and revised its estimate of the one-time initial cost per SDR to be in a range of $144,000 to $1,010,000 for PRA purposes, based on 3,000 to 10,000 hours of work per SDR.[4] Using these revised estimates, the Commission estimated an average estimated cost of $577,000 per SDR to update their systems, or estimated capital/start-up costs of $1,731,000 across all 3 SDRs.

With regard to reporting entities, the PRA section of the proposal inadvertently did not include any estimates of initial costs to update systems for SEFs, DCMs, and reporting counterparties. In the final rule, the Commission estimated that SEFs, DCMs, and reporting counterparties will incur a one-time initial cost per reporting entity in a range of $24,000 to $73,225 per reporting entity, with each reporting entity spending approximately 500 to 725 hours on the updates.[5] Rather than base the Commission's PRA estimates of the total upfront implementation cost for reporting entities on arithmetic averages, the Commission recognized that reporting entities are already subject to existing swaps data reporting and recordkeeping obligations pursuant to Part 45, so it is likely that reporting entities will only need to reprogram their existing reporting systems, instead of building new reporting systems, to comply with the final rule. Furthermore, through the Commission's eight years of experience in administering Part 45, the Commission believes that the 1,732 reporting entities are a relatively consistent group, such that most entities that are currently reporting entities under Part 45 will continue to be reporting entities under the final rule, and few entities that are not currently reporting entities under Part 45 will become reporting entities under the final rule. Because most reporting entities will only need to reprogram their existing reporting systems, the Commission believes that the upfront cost to reporting entities to implement the final rule will be on the lower end of the range, closer to $24,000 than to $73,225. Therefore, the Commission based its PRA estimates on a more realistic split of 90%/10% between existing reporting entities and new reporting entities, which resulted in a weighted average cost of $28,923 per reporting entity ($24,000 * 0.9 + $73,225 * 0.1), or a total upfront implementation cost of $50,094,636 for the 1,732 reporting entities.

Together, the Commission estimated the total aggregate upfront implementation cost in the final rule to be $51,825,636 ($50,094,636 for reporting entities and $1,731,000 for SDRs). The Commission does not expect any ongoing costs for SDRs or reporting entities after the initial builds.

2. Amendments to Regulation 45.4

The Commission amended § 45.4, which requires reporting counterparties to report data to SDRs when swap terms change and daily swap valuation data. The PRA section of the Proposal estimated that proposed § 45.4 would apply to 1,705 respondents, with 97,341 reports per respondent, .004 average hours per report, and a gross annual reporting burden of 664,479 hours. In the final rule, the Commission expanded the daily valuation data reporting requirement for SD/MSP reporting counterparties to report margin and collateral data in addition to valuation data. This is a change from the Proposal, in which the Commission proposed requiring derivatives clearing organization (''DCO'') counterparties to report the information as well. The frequency of the report will not change for SD/MSP reporting counterparties, but the Commission estimated SD/MSP/DCO reporting counterparties would require more time to prepare each report. However, since all of this information is reported electronically, the Commission expected the increase per report to be small, from .003 to .004 hours per report. Since the Commission is not requiring DCO reporting counterparties to report the information, the Commission revised its estimate to .0035 hours per report. As a result, in the final rule the aggregate burden under § 45.4 was estimated to apply to 1,705 respondents, with 97,341 reports per respondent, .0035 average hours per report, and a gross annual reporting burden of 581,419 hours.

Amended § 45.4 creates costs for SDRs and reporting counterparties to update systems for reporting required swap continuation data. For the proposal, the Commission estimated SDRs and reporting counterparties would incur a one-time initial burden of 10 hours per entity to modify their systems to adopt the changes to § 45.4, for a total estimated hours burden of 17,050 hours. The cost per entity was estimated to be $722.30 for a total cost across entities of $1,231,522. The Commission additionally estimated 5 hours per entity annually to perform any needed maintenance or adjustments to reporting systems, at a cost of $361.15 per entity and $615,761 across entities. However, the Commission re-evaluated the analysis for the final rule and realized that since the costs relate to reporting certain swap data elements, they are covered in the start-up and initial costs for § 45.3 described above. To avoid double-counting, the Commission removed the estimates for § 45.4.

2. Amendments to Regulation 45.5

Amended § 45.5 creates costs for entities that were previously required to generate Unique Swap Identifiers (''USIs'') to update their systems to generate Uniform Transaction Identifiers (''UTIs''). The PRA section of the Proposal estimated that SDRs and reporting counterparties required to generate UTIs would incur a one-time initial burden of 1 hour per entity to modify their systems to adopt the changes to § 45.5, for a total estimated hours burden of 940 hours. The Commission additionally estimated 1 hour per entity annually to perform any needed maintenance or adjustments to reporting systems. The related Supporting Statement filed with OMB for the Proposal estimated that the cost per entity for the one-time initial burden would be $72.23 for a total cost across entities of $67,896, and an additional cost of $72 per entity and $67,680 across entities annually to perform any needed maintenance or adjustments to reporting systems. The PRA section of the final rule did not make any changes to the Commission's burden hour estimates for SDRs and reporting counterparties to modify their systems to adopt the changes to final § 45.5 in connection with either its estimates of either the one-time initial burden estimate or the burden of ongoing maintenance or adjustments to reporting systems. The final rule also did not change the estimated cost per entity of $72.23 per entity or a total cost across entities of $67,896 in connection with the Commission's estimate of the one-time

benefits (rounded to the nearest whole dollar) which is in line with adjustment factors the CFTC has used for similar purposes in other final rules adopted under the Dodd-Frank Act. *See, e.g.,* 77 FR at 2173 (using an adjustment factor of 1.3 for overhead and other benefits). These estimates are intended to capture and reflect U.S. developer hourly rates market participants are likely to pay when complying with the changes. Individual entities may, based on their circumstances, incur costs substantially greater or less than the estimated averages.

[4] The lower estimate of $144,000 represents 3,000 working hours at the $48 rate. The higher estimate of $1,010,000 represents 10,000 working hours at the $101 rate. The PRA section of the final rule incorrectly stated that the $1,010,000 estimate at the higher end of the range was based on 5,000 working hours. However, in response to a comment indicating that the commenter expected its costs to be 8,000 to 10,000 developer hours, the Commission expanded the range of potential costs per SDR to between $144,000 and $1,010,000 for PRA purposes.

[5] The lower estimate of $24,000 represents 500 working hours at the $48 rate. The higher estimate of $73,225 represents 725 working hours at the $101 rate.

initial burden costs for SDRs and reporting counterparties required to generate UTIs. However, the PRA section of the final rule corrected the estimated cost per entity for ongoing maintenance or adjustment to reporting systems in the supporting statement for the Proposal from a cost of $72 per entity and $67,680 across entities to a cost of $72.23 per entity and $67,896 across entities for final § 45.5.

With respect to the collection of information, the Commission invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of collection of information on those who are to respond, including through the use of appropriate electronic, or other forms of information technology, *e.g.,* permitting electronic submission of responses.

You should submit only information that you wish to make available publicly. If you wish the CFTC to consider information that you believe is exempt from disclosure under the Freedom of Information Act (''FOIA''), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the CFTC's regulations.[6]

The CFTC reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *https://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under FOIA.

Burden Statement: Provisions of CFTC Regulations 45.2, 45.3, 45.4, 45.5, 45.6, 45.10 and 45.14 result in information collection requirements within the meaning of the PRA. With respect to the ongoing reporting and recordkeeping burdens associated with swaps, the CFTC believes that SEFs, DCMs, DCOs, SDRs, swap dealers (''SDs''), major swap participants (''MSPs''), and non-SD/MSP/DCO counterparties incur an annual time-burden of 1,226,021 hours. This time-burden represents a proportion of the burden respondents incur to operate and maintain their swap data recordkeeping and reporting systems.

Respondents/Affected Entities: SDs, MSPs, SDRs, DCMs, SEFs, and other counterparties to a swap transaction (*i.e.,* non-SD/MSP/DCO counterparties).

Estimated number of respondents: 1,732.

Estimated average burden hours per respondent: 708.

Estimated total annual burden hours on respondents: 1,226,021 hours.

Frequency of collection: Ongoing.

Capital or Operating and Maintenance Costs: $ 51,961,428.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: November 27, 2020.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–26556 Filed 12–1–20; 8:45 am]

BILLING CODE 6351–01–P

[6] 17 CFR 145.9.

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Proposed Revised Collection, Comment Request: ''Real Time Public Reporting''

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is announcing an opportunity for public comment on the revision of an information collection by the agency. Under the Paperwork Reduction Act of 1995 (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each revised collection of information and to allow 60 days for public comment. The Commission recently adopted a final rule amending requirements for the real-time public reporting and dissemination of swap data. This notice solicits additional comments on certain estimated costs and burdens associated with the amended requirements.

DATES: Comments must be submitted on or before February 1, 2021.

ADDRESSES: You may submit comments, identified by ''Real Time Public Reporting, OMB Control No. 3038–0070,'' by any of the following methods:

- The Agency's website, at *http://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Meghan Tente, Acting Deputy Director, Division of Market Oversight, Commodity Futures Trading Commission, (202) 418–5785, email: *mtente@cftc.gov,* and refer to OMB Control No. 3038–0070.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (''OMB'') for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed information collection including each proposed revision or extension of an existing information collection, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Title: Real Time Public Reporting and Block Trades (OMB Control No. 3038–0070). This is a request for comment on a currently approved information collection.

Abstract: The collection of information is needed to ensure that swap data repositories publicly disseminate swap data as required by the Commodity Exchange Act, as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''). The Dodd-Frank Act directed the CFTC to adopt rules providing for the real-time public

reporting and dissemination of swap data and rules for block trades.

On September 17, 2020, the Commission adopted a rulemaking amending its part 43 regulations.[1] In the release accompanying the Final Rule, the Commission included some cost and burden estimates that were not included in the Proposal, including changes to some of its previous estimates.[2] The Commission explains these cost and burden estimates further below and invites comment on any new or revised estimates.

1. Amendments to Regulation 43.3

In the Proposal, the Commission omitted the aggregate reporting burden for proposed § 43.3 (as well as § 43.4) and instead provided PRA estimates for all of part 43. The Final Rule included the estimated aggregate reporting burden for § 43.3 as follows:

Estimated number of respondents: 1,729 SEFs, DCMs, and reporting counterparties.

Estimated number of reports per respondent: 2,998.

Average number of hours per report: 0.067.

Estimated gross annual reporting burden: 725,696.

Existing § 43.3 requires reporting counterparties to send swap reports to swap data repositories (''SDRs'') as soon as technologically practicable after execution. The Commission did not include any burden estimates in the Proposal related to the modification or maintenance of systems in order to be in compliance with the proposed amendments to § 43.3.[3] However, for the Final Rule, the Commission recognized certain entities would incur start-up costs to modify their reporting systems and operational costs to maintain them going forward to adopt the changes to § 43.3[4] in the Final Rule, as explained below.

In the Final Rule, the Commission estimated the cost for a reporting entity, including designated contracts markets (''DCMs''), derivatives clearing organizations (''DCOs''), major swap participants (''MSPs''), swap dealers (''SDs''), non-SD/MSP/DCO counterparties, and swap execution facilities (''SEFs''), to modify their systems and maintain those modifications going forward to adopt the Final Rule could range from $24,000 to $74,000 per entity. There are an estimated 1,732 reporting entities, for a total estimated cost of $84,868,000.[5] As described in the final rule, the estimated cost range is based on a number of assumptions that cover tasks required to design, test, and implement an updated data system based on the new swap data elements contained in part 43.

In the Final Rule, the Commission further estimated that the cost for an SDR to modify their systems, including their data reporting, ingestion, and validation systems, and maintain those modifications going forward may range from $144,000 to $510,000 per SDR. There are currently three SDRs, for an estimated total cost of $981,000.[6]

2. Amendments to Regulation 43.4

In the Final Rule, the Commission estimated that the amendments would reduce the number of mirror swaps SDRs would need to publicly disseminate by 100 reports per each SDR, for an aggregate burden hour reduction of 20.10 hours. In addition, the Commission estimated that the aggregate reporting burden total for § 43.4, as adjusted for the reduction in reporting by SDRs of mirror swaps, is as follows:

Estimated number of respondents: 3.

Estimated number of reports per respondent: 1,499,900.

Average number of hours per report: 0.009.

Estimated gross annual reporting burden: 40,497.

The Commission did not include any burden estimates in the Proposal related to the modification or maintenance of systems in order to be in compliance with the proposed amendments to § 43.4. To avoid double-counting, the Commission included the costs associated with updates to § 43.4 in the estimates for § 43.3 discussed above, as they would be captured in the costs of updating systems based on the list of swap data elements in part 43.

The Commission is soliciting comments on the above burden estimates for part 43, including the estimated costs related to the modification or maintenance of systems in order to be in compliance with the amendments to § 43.3 that are being adopted in the Final Rule, in this separate 60-day notice being published in the **Federal Register**.

With respect to the collection of information, the Commission invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of collection of information on those who are to respond, including through the use of appropriate electronic, or other forms of information technology, *e.g.,* permitting electronic submission of responses.

You should submit only information that you wish to make available publicly. If you wish the CFTC to consider information that you believe is exempt from disclosure under the Freedom of Information Act (''FOIA''), a petition for confidential treatment of the exempt information may be submitted

[1] The Commission proposed the amendments to Part 43 in February 2020. Real-Time Public Reporting Requirements, 85 FR 21516 (Apr. 17, 2020) (the ''Proposal''). The final rule was published in the **Federal Register** on November 25, 2020 (the ''Final Rule'').

[2] In the final rule, the Commission revised the information collection to reflect the adoption of amendments to part 43, including changes to reflect adjustments that were made to the final rules in response to comments on the Proposal (not relating to PRA). In the Proposal, the Commission omitted the aggregate reporting burden for proposed § 43.3 and § 43.4 in the preamble and instead provided PRA estimates for all of part 43. In the final rule, the Commission included PRA estimates for final § 43.3 and § 43.4 which are set forth below. In addition, in the final rule, the Commission revised the information collection to include burden estimates for one-time costs that SDRs, SEFs, DCMs, and reporting counterparties could incur to modify their systems to adopt the changes to part 43, as well as burden estimates for these entities to perform any annual maintenance or adjustments to reporting systems related to the changes. These estimates are also set forth below. The Commission did not include PRA estimates for all of part 43 in the final rule as the final rule only affects PRA estimates for § 43.3 and § 43.4. However, PRA estimates for all of part 43 are included in the supporting statement being filed with OMB in connection with the final rule.

[3] The supporting statement for part 43 submtted for the Proposal only showed negative incremental changes in Attachment A (*e.g.,* showed a negative adjustment of 30,300 responses and negative 2,030.10 burden hours).

[4] The Commission did not include any burden estimates in the final rule related to the modification or maintenance of systems in order to be in compliance with the amendments to § 43.4. To avoid double-counting, the Commission included the costs associated with updates to § 43.4 in the estimates for § 43.3, as they would be captured in the costs of updating systems based on the list of swap data elements in part 43. As noted above, the Commission is soliciting comments on the revised burden estimates for part 43 that are being adopted in the final rule.

[5] Based on the Commission's eight years of experience in administering the existing-real time reporting regulation, the Commission believes that the costs to reporting entities to implement the final rule will be on the lower end of the range, closer to $24,000 than to $74,000.

[6] As described in the Final Rule, the estimated cost ranges are based on a number of assumptions that cover the set of tasks required for the SDR to design, test, and implement an updated data system based on the new swap data elements contained in part 43.

according to the procedures established in § 145.9 of the CFTC's regulations.[7]

The CFTC reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under FOIA.

Burden Statement: Provisions of CFTC Regulations 43.3, 43.4, and 43.6 result in information collection requirements within the meaning of the PRA. With respect to the ongoing reporting and recordkeeping burdens associated with swaps, the CFTC believes that SDs, MSPs, SEFs, DCMs, DCOs, and non-SD/MSP/DCO counterparties incur an annual time-burden of 771,831 hours. This time-burden represents a proportion of the burden respondents incur to operate and maintain their swap data recordkeeping and reporting systems.

Respondents/Affected Entities: SDs, MSPs, and other counterparties to a swap transaction (*i.e.,* non-SD/MSP/DCO counterparties).

Estimated number of respondents: 1,732.

Estimated average burden hours per respondent: 445.

Estimated total annual burden hours on respondents: 771,831 hours.

Frequency of collection: Ongoing.

Capital or Operating and Maintenance Costs: $85,849,000.[8]

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: November 27, 2020.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–26557 Filed 12–1–20; 8:45 am]

BILLING CODE 6351–01–P

[7] 17 CFR 145.9.

[8] In the Proposal, the Commission omitted the aggregate reporting burden for proposed § 43.3 and § 43.4 in the preamble and instead provided PRA estimates for all of part 43. In the final rule, the Commission included PRA estimates for final § 43.3 and § 43.4 because these are the only sections of part 43 affected by the final rulemaking. Attachment A to the supporting statement for the Proposal only showed the changes in the burden estimates for § 43.3 and § 43.4 for the Proposal. For the Final Rule, the Commission revised Attachment A to the supporting statement that was filed with OMB to include aggregate burden estimates for all requirements in the collection. The estimates in the supporting statements for the Final Rule are consistent with the estimates shown in the Burden Statement above (*e.g.,* the supporting statement for the Final Rule reflects that there are 1,732 respondents and that the total annual number of burden hours across all respondents is 771,831.)

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–43]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 20–43 with attached Policy Justification and Sensitivity of Technology.

Dated: November 25, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

September 30, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-43 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of Switzerland for defense articles and services estimated to cost $2.2 billion. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 20–43

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as Amended

(i) *Prospective Purchaser:* Government of Switzerland.

(ii) *Total Estimated Value:*

Major Defense Equipment *	$1.1 billion
Other	$1.1 billion
Total	$2.2 billion

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* The Government of Switzerland has requested the possible sale of five (5) Patriot Configuration-3+ Modernized Fire Units, consisting of:

Major Defense Equipment (MDE):
- Five (5) AN/MPQ–65 Radar Sets
- Five (5) AN/MSQ–132 Engagement Control Stations
- Seventeen (17) M903 Launching Stations
- Up to seventy (70) Patriot MIM–104E Guidance Enhanced Missile Tactical (GEM–T) Missiles
- Seven (7) Antenna Mast Groups
- Five (5) Electrical Power Plants (EPP) III
- Six (6) Multifunctional Information Distribution System Low Volume Terminal (MIDS–LVT) (11) Block Upgrade Two (BU2)

Non-MDE: Communications equipment; tools and test equipment; range and test programs; support equipment to include associated vehicles; prime movers; generators; publications and technical documentation; training equipment; spare and repair parts; personnel training; Technical Assistance Field Team (TAFT); U.S. Government and contractor technical, engineering, and logistics support services; Systems Integration and Checkout (SICO); field office support; and other related elements of logistics and program support.

(iv) *Military Department:* Army (SZ–B–UAS).

(v) *Prior Related Cases, if any:* None.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* September 30, 2020.

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Switzerland—Patriot Configuration-3+ Modernized Fire Units

The Government of Switzerland has requested the possible sale of five (5) Patriot Configuration-3+ Modernized Fire Units, consisting of: five (5) AN/MPQ–65 Radar Sets; five (5) AN/MSQ–132 Engagement Control Stations;

seventeen (17) M903 Launching Stations; up to seventy (70) Patriot MIM–104E Guidance Enhanced Missile Tactical (GEM–T) Missiles; seven (7) Antenna Mast Groups; five (5) Electrical Power Plants (EPP) III; and six (6) Multifunctional Information Distribution System Low Volume Terminal (MIDS–LVT) (11) Block Upgrade Two (BU2). Also included are communications equipment; tools and test equipment; range and test programs; support equipment to include associated vehicles; prime movers; generators; publications and technical documentation; training equipment; spare and repair parts; personnel training; Technical Assistance Field Team (TAFT); U.S. Government and contractor technical, engineering, and logistics support services; Systems Integration and Checkout (SICO); field office support; and other related elements of logistics and program support. The total estimated cost is $2.2 billion.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security of a friendly European nation which is an important force for political stability and economic progress within Europe.

The proposed sale of the Patriot missile system will improve Switzerland's missile defense capability. Switzerland will use the Patriot to defend its territorial integrity and for regional stability. The proposed sale supports Switzerland's goal of improving national and territorial defense. Switzerland will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractors will be Raytheon Corporation, Tewksbury, Massachusetts and Lockheed-Martin, Dallas, Texas. The purchaser typically requests offsets. Any offset agreement will be defined in negotiations between the purchaser and the contractor.

Implementation of this proposed sale will require approximately twenty-five (25) U.S. Government and forty (40) contractor representatives to travel to Switzerland for an extended period for equipment de-processing/fielding, system checkout, training, and technical and logistics support.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 20–43

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The Patriot Air Defense System is a surface-to-air missile defense system, which continues to hold a significant technology lead over other systems in the world. The Patriot Air Defense System contains communication, identification, navigation, and tactical software. The items requested represent significant technological advances for Switzerland.

2. The Patriot sensitive/critical technology is primarily in the area of design and production know-how and inherent in the design, development and/or manufacturing data related to certain components.

3. The highest level of classification of defense articles, components, services, and information on system performance capabilities, effectiveness, survivability, missile seeker capabilities, select software/software documentation and test data included in this potential sale are classified up to and including SECRET.

4. Loss of this hardware, software, documentation and/or data could permit development of information which may lead to a significant threat to future U.S. military operations. If an adversary were to obtain this sensitive technology, the missile system effectiveness could be compromised through reverse engineering techniques.

5. A determination has been made that Switzerland can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

6. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Switzerland.

[FR Doc. 2020–26544 Filed 12–1–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–63]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 20–63 with attached Policy Justification and Sensitivity of Technology.

Dated: November 25, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

September 28, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-63 concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Japan for defense articles and services estimated to cost $55.311 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 20–63

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as Amended

(i) *Prospective Purchaser:* Government of Japan.

(ii) *Total Estimated Value:*

Major Defense Equipment *.	$50.311 million
Other	$ 5.000 million
Total	$55.311 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Up to fifty-one (51) Rolling Airframe Missiles (RAM) Block 2 Tactical Missiles, RIM–116C

*Non-MDE:*Also included are RAM Guided Missile Round Pack Tri-Pack shipping and storage containers, operator manuals and technical documentation, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistical and program support.

(iv) *Military Department:* Navy (JA–P–AUF).

(v) *Prior Related Cases, if any:* JA–P–ATK.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* September 28, 2020.

* As defined in Section 47(6) of the Arms Export Control Act.

Policy Justification

Japan—RAM Block 2 Tactical Missiles

The Government of Japan has requested to buy up to fifty-one (51) Rolling Airframe Missiles (RAM) Block 2 Tactical Missiles, RIM–116C. Also included are RAM Guided Missile Round Pack Tri-Pack shipping and storage containers, operator manuals and technical documentation, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistical and program support. The estimated total cost is $55.311 million.

This proposed sale will support the foreign policy goals and national security objectives of the United States by improving the security of a major ally that is a force for political stability and economic progress in the Asia-Pacific region. It is vital to U.S. national interest

to assist Japan in developing and maintaining a strong and effective self-defense capability.

These RAM Block 2 Tactical missiles will provide significantly enhanced area defense capabilities over critical East Asian and Western Pacific air and sea-lines of communication. Japan will have no difficulty absorbing these missiles into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be Raytheon Missiles and Defense Company, Tucson, AZ. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this sale will not require the assignment of U.S. Government or contractor representatives in Japan.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 20–63

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The RIM–116C Rolling Airframe Missile (RAM) is an autonomous (*i.e.,* ''fire and forget'') lightweight, supersonic, surface-to-air tactical missile for ship self-defense against current and evolving anti-ship cruise missile threats. Advanced technology in the RIM–116C includes dual-mode RF/IR (radio frequency/infrared) guidance with IR all-the-way capability for non-emitting threats.

2. The Rolling Airframe Missile (RAM) is a product of a cooperative program with Germany and has been executed, since 1976, under a series of governing Memoranda of Understanding/Memoranda of Agreements (MOU/MOAs) for the development, production, and in-service support between the United States and Germany.

3. The highest level of classification of information included in this potential sale is CONFIDENTIAL.

4. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

5. A determination has been made that Japan can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furthering U.S. foreign policy and national security objectives outlined in the Policy Justification.

6. All defense articles and services listed in this transmittal have been authorized for release and export to Japan.

[FR Doc. 2020–26539 Filed 12–1–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–70]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 20–70 with attached Policy Justification and Sensitivity of Technology.

Dated: November 25, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

September 30, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-70, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of India for defense articles and services estimated to cost $90 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 20–70

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as Amended

(i) *Prospective Purchaser:* Government of India.

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ 0 million
Other	$90 million
Total	$90 million

(iii) *Description and Quantity or Quantities of Articles or Services under consideration for Purchase:* The Government of India has requested to buy items and services to extend follow-on support for its fleet of C–130J Super Hercules aircraft. These items include:

Major Defense Equipment (MDE): None

Non-MDE: Aircraft consumables spares and repair/return parts; ground support and equipment; Cartridge Actuated Devices/Propellant Actuated Devices (CAD/PAD) fire extinguisher cartridges; flare cartridges; BBU–35/B cartridge impulse squibs; one spare AN/ALR–56M Advanced Radar Warning Receiver shipset; spare AN/ALE–47 Counter-Measures Dispenser System shipset; ten Lightweight Night Vision Binocular (F5032); ten AN/AVS–9 Night Vision Goggle (NVG)(F4949); GPS; Electronic Warfare; instruments and lab equipment support; Joint Mission Planning System; cryptographic device spares and loaders; software and software support; publications and technical documentation; personnel training and training and training equipment; U.S. and contractor engineering, technical, and logistical support; and other related elements of program support.

(iv) *Military Department:* Air Force (IN–D–QAH).

(v) *Prior Related Cases, if any:* IN–D–SAA, IN–D–SAD, IN–D–QAE.

(vi) *Sales Commission, Fee, etc. Paid, Offered, or Agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* September 30, 2020.

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

India—C–130J Follow-on Support

The Government of India has requested to buy items and services to extend follow-on support for their fleet of C–130J Super Hercules aircraft. These items include aircraft consumables spares and repair/return parts; ground support and equipment; Cartridge Actuated Devices/Propellant Actuated

Devices (CAD/PAD) fire extinguisher cartridges; flare cartridges; BBU–35/B cartridge impulse squibs; one spare AN/ALR–56M Advanced Radar Warning Receiver shipset; spare AN/ALE–47 Counter-Measures Dispenser System shipset; ten Lightweight Night Vision Binocular (F5032); ten AN/AVS–9 Night Vision Goggle (NVG)(F4949); GPS; Electronic Warfare; instruments and lab equipment support; Joint Mission Planning System; cryptographic device spares and loaders; software and software support; publications and technical documentation; personnel training and training and training equipment; U.S. and contractor engineering, technical, and logistical support; and other related elements of program support. The estimated total case value is $90 million.

This proposed sale will support the foreign policy and national security of the United States by helping to strengthen the U.S.-Indian strategic relationship and improve the security of a major defensive partner, which continues to be an important force for political stability, peace, and economic progress in the Indo-Pacific and South Asia region

The proposed sale ensures the previously procured aircraft operates effectively to serve the needs of Indian Air Force, Army and Navy transport requirements, local and international humanitarian assistance, and regional disaster relief. This sale of spares and services will enable the Indian Air Force to sustain a mission-ready status with respect to the C–130J transport. India will have no difficulty absorbing this additional sustainment support.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be Lockheed-Martin Company, Marietta, Georgia. There are no known offsets proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives India.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 20–70

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AN/ALR–56M is a computer controlled radar warning receiver (RWR). It monitors the environment in an effort to detect radar signals. Upon detection and identification of a valid radar signal, emitter identification is conveyed to the AN/ALE–47 countermeasures dispenser system. The ALR–56M has thirteen line replaceable units (LRUs): four I/J band DF receivers, an Analysis Processor, a Superhet Controller, a Superhet Receiver, a C/D band Receiver/Power supply, four I/J band antennas, and one C/D band antenna.

2. The AN/ALE–47 Counter-Measures Dispensing System (CMDS) is an integrated, threat-adaptive, software-programmable dispensing system capable of dispending chaff, flares, and active radio frequency expendables. The system is internally mounted and may be operated as a stand-alone system or may be integrated with other on-board electronic warfare and avionics systems. The AN/ALE–47 uses data received over the aircraft interfaces to assess the threat situation and to determine a response.

3. The highest level of classification of information included in this potential sale is SECRET.

4. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

5. A determination has been made that the recipient country can provide the same degree of protection for the sensitive technology being released as the U.S. Government. The sale is necessary in furtherance of the U.S. foreign policy and national security objectives outline in the Policy Justification.

6. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of India.

[FR Doc. 2020–26541 Filed 12–1–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–76]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 20–76 with attached Policy Justification.

Dated: November 25, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

September 24, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-76 concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of the United Kingdom for defense articles and services estimated to cost $401.3 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification

BILLING CODE 5001–06–C

Transmittal No. 20–76

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as Amended

(i) *Prospective Purchaser:* The Government of the United Kingdom.

(ii) *Total Estimated Value:*

Major Defense Equipment *.	$ 0.0 million
Other	$401.3 million
Total	$401.3 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): None

Non-MDE: Follow-on C–17 aircraft Contractor Logistical Support (CLS) to include aircraft component spare and repair parts; accessories; publications and technical documentation; software and software support; U.S. Government and contractor engineering, technical and logistical support services; and other related elements of logistical and program support

(iv) *Military Department:* Air Force (UK–D–QDQ).

(v) *Prior Related Cases, if any:* UK–D–QDD.

(vi) *Sales Commission, Fee, etc., Paid Offered, or Agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None.

(viii) *Date Report Delivery to Congress:* September 24, 2020.

* As defined in Section 47(6) of the Arms Exports Control Act.

POLICY JUSTIFICATION

United Kingdom—Follow-on Contractor Logistics Support (CLS) for C–17 Aircraft

The Government of the United Kingdom has requested to buy follow-on C–17 aircraft Contractor Logistical Support (CLS) to include aircraft component spare and repair parts; accessories; publications and technical documentation; software and software support; U.S. Government and contractor engineering, technical and logistical support services; and other related elements of logistical and program support. The total estimated program cost is $401.3 million.

This proposed sale will support the foreign policy and national security objectives of the United States by improving the security of a key NATO Ally, which is an important force for political stability and economic progress in Europe.

This proposed sale will improve the United Kingdom's capability to meet current and future threats by ensuring the operational readiness of the Royal Air Force. Its C–17 aircraft fleet provides strategic airlift capabilities that directly support U.S. and coalition

operations around the world. The United Kingdom will have no difficulty absorbing these services into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be The Boeing Company of Chicago, IL. There are no known offset agreements proposed in connection with this potential sale.

Implementation of the proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to the United Kingdom.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2020–26542 Filed 12–1–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–59]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 20–59 with attached Policy Justification and Sensitivity of Technology.

Dated: November 25, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

September 24, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-59 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of the Netherlands for defense articles and services estimated to cost $241 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C?

Transmittal No. 20–59

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of the Netherlands

(ii) *Total Estimated Value:*

Major Defense Equipment *	$194 million
Other	$ 47 million
TOTAL	$241 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Thirty-four (34) Patriot Advanced Capability-3 (PAC–3) Missile Segment Enhancement (MSE) Missiles.

Non-MDE: Also included are eight (8) kitted 2-pack PAC–3 MSE Missile Round Trainers (MRT), six (6) kitted 2-pack PAC–3 MSE Empty Round Trainers (ERT), four (4) PAC–3 MSE Skid Kits, one (1) Lot of Classified PAC–3 MSE Concurrent Spare Parts (CSPs), one (1) Lot of Unclassified PAC–3 MSE CSPs, and PAC–3 MSE repair and return processing support services, and other related elements of logistics and program support.

(iv) *Military Department:* Army (NE–B–YAF)

(v) *Prior Related Cases, if any:* NE–B–WBV

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* September 24, 2020

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

The Netherlands—Patriot Advanced Capability-3 (PAC–3) Missile Segment Enhancement (MSE) Missiles

The Government of the Netherlands has requested to buy thirty-four (34) Patriot Advanced Capability-3 (PAC–3) Missile Segment Enhancement (MSE) missiles. Also included are eight (8) kitted 2-pack PAC–3 MSE Missile Round Trainers (MRT), six (6) kitted 2-pack PAC–3 MSE Empty Round Trainers (ERT), four (4) PAC–3 MSE Skid Kits, one (1) Lot of Classified PAC–3 MSE Concurrent Spare Parts (CSPs), one (1) Lot of Unclassified PAC–3 MSE CSPs, and PAC–3 MSE repair and return processing support services, and other related elements of logistics and program support. The total estimated program cost is $241 million.

This proposed sale will support the foreign policy and national security of the United States by helping to improve security of a NATO ally which is an important force for political stability and economic progress in Northern Europe.

This proposed sale will improve the Netherlands' missile defense capability to meet current and future enemy threats. The Netherlands will use the enhanced capability to strengthen its homeland defense and deter regional threats, and provide direct support to coalition and security cooperation efforts. The Netherlands will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be Lockheed-Martin, Dallas, TX. The purchaser typically requests offsets. Any offset agreement will be defined in negotiations between the purchaser and the contractor(s).

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to the Netherlands.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 20–59

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The Patriot Advanced Capability (PAC–3) Missile Segment Enhancements (MSE) is a small, highly agile, kinetic kill interceptor for defense against tactical ballistic missiles, cruise missiles and air-breathing threats. The MSE variant of the PAC–3 missile represents the next generation in hit-to-kill interceptors and provides expanded battlespace against evolving threats. The PAC–3 MSE improves upon the original PAC–3 capability with a higher performance solid rocket motor, modified lethality enhancer, more responsible control surfaces, upgraded guidance software and insensitive munitions improvements.

2. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that the Netherlands can provide substantially the same degree of protection for the technology being released as the U.S. Government. This potential sale is necessary in furtherance of the U.S. foreign policy and national security objectives as outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Netherlands.

[FR Doc. 2020–26538 Filed 12–1–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–34]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 20–34 with attached Policy Justification and Sensitivity of Technology.

Dated: November 25, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

September 30, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-34 concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Switzerland for defense articles and services estimated to cost $7.452 billion. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 20–34

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as Amended

(i) *Prospective Purchaser:* Government of Switzerland.

(ii) *Total Estimated Value:*

Major Defense Equipment *	$4.155 billion
Other	$3.297 billion
Total	$7.452 billion

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):
Thirty-six (36) F/A–18E Super Hornet Aircraft
Seventy-two (72) F414–GE–400 Engines (Installed)
Four (4) F/A–18F Super Hornet Aircraft
Eight (8) F414–GE–400 Engines (Installed)
Sixteen (16) F414–GE–400 Engines (Spares)
Forty-four (44) M61A2 20MM Gun Systems
Twenty-five (25) Advanced Targeting Forward-Looking Infrared (ATFLIR)
Fifty-five (55) AN/ALR–67(V)3 Electric Warfare Countermeasures Receiving Sets
Fifty-five (55) AN/ALQ–214 Integrated Countermeasures Systems
Forty-eight (48) Multifunctional Information Distribution Systems—Joint Tactical Radio Systems (MIDS JTRS)
Forty-eight (48) Joint Helmet Mounted Cueing Systems (JHMCS)
Two hundred sixty-four (264) LAU–127E/A Guided Missile Launchers
Forty-eight (48) AN/AYK–29 Distributed Targeting Processor—Networked (DTP–N)
Twenty-seven (27) Infrared Search and Track (IRST) Systems
Forty (40) AIM–9X Block II Sidewinder Tactical Missiles
Fifty (50) AIM–9X Block II Sidewinder Captive Air Training Missiles (CATMs)
Six (6) AIM–9X Block II Sidewinder Special Air Training Missiles (NATMs)
Four (4) AIM–9X Block II Sidewinder Tactical Guidance Units
Ten (10) AIM–9X Block II Sidewinder CATM Guidance Units
Eighteen (18) KMU–572 JDAM Guidance Kits for GBU–54
Twelve (12) Bomb MK–82 500LB, General Purpose
Twelve (12) Bomb MK–82, Inert
Twelve (12) GBU–53/B Small Diameter Bomb II (SDB II) All-Up Round (AUR)
Eight (8) GBU–53/B SDB II Guided Test Vehicle (GTV)

Non-MDE: Also included are AN/APG–79 Active Electronically Scanned Array (AESA) radars; High Speed Video Network (HSVN) Digital Video Recorder (HDVR); AN/AVS–9 Night Vision Goggles (NVG); AN/AVS–11 Night

Vision Cueing Device (NVCD); AN/ALE–47 Electronic Warfare Countermeasures Systems; AN/ARC–210 Communication System; AN/APX–111 Combined Interrogator Transponder; AN/ALE–55 Towed Decoys; launchers (LAU–115D/A, LAU–116B/A, LAU118A); Training Aids, Devices and Spares; Technical Data Engineering Change Proposals; Avionics Software Support; Joint Mission Planning System (JMPS); Data Transfer Unit (DTU); Accurate Navigation (ANAV) Global Positioning System (GPS) Navigation; KIV–78 Dual Channel Encryptor, Identification Friend or Foe (IFF); Cartridge Actuated Devices/Propellant Actuated Devices (CADs/PADs); Technical Publications; AN/PYQ–10C Simple Key Loader (SKL); Aircraft Spares; other support equipment; Aircraft Armament Equipment (AAE); aircraft ferry; transportation costs; other technical assistance; engineering technical assistance; contractor engineering technical support; logistics technical assistance; Repair of Repairables (RoR); aircrew and maintenance training; contractor logistics support; flight test services; Foreign Liaison Officer (FLO) support; auxiliary fuel tanks, system integration and testing; software development/integration; and other related elements of logistics and program support. For AIM–9X: Containers; missile support and test equipment; provisioning; spare and repair parts; personnel training and training equipment; publications and technical data; and U.S. Government and contractor technical assistance and other related logistics support. For GBU–53/B SDB II and GBU–54: Detector Laser DSU–38A/B, Detector Laser DSU–38A(D–2)/B, FMU–139D/B Fuze, KMU–572(D–2)/B Trainer (JDAM), 40-inch Wing Release Lanyard; GBU–53/B SDB II Weapon Load Crew Trainers (WLCT); weapons containers; munitions support and test equipment; spares and repair parts; repair and return support; personnel training and training equipment; publications and technical documents; U.S. Government and contractor engineering, technical, and logistics support services; and other related elements of logistical and program support.

(iv) *Military Department:* Navy (SZ–P–SAZ, SZ–P–LAZ, SZ–P–SBZ); Air Force.

(SZ–D–YAD).

(v) *Prior Related Cases, if any:* None.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* September 30, 2020.

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Switzerland—F/A–18E/F Super Hornet Aircraft and Weapons

The Government of Switzerland has requested to buy up to thirty-six (36) F/A–18E Super Hornet aircraft; seventy-two (72) F414–GE–400 engines (installed); four (4) F/A–18F Super Hornet aircraft; eight (8) F414–GE–400 engines (installed); sixteen (16) F414–GE–400 engines (spares); forty-four (44) M61A2 20MM gun systems; twenty-five (25) Advanced Targeting Forward-Looking Infrared (ATFLIR)/other targeting pod; fifty-five (55) AN/ALR–67(V)3 Electric Warfare Countermeasures Receiving sets; fifty-five (55) AN/ALQ–214 Integrated Countermeasures systems; forty-eight (48) Multifunctional Information Distribution Systems—Joint Tactical Radio Systems (MIDS–JTRS); forty-eight (48) Joint Helmet Mounted Cueing Systems (JHMCS); two hundred sixty-four (264) LAU–127E/A guided missile launchers; forty-eight (48) AN/AYK–29 Distributed Targeting Processor—Networked (DTP–N); twenty-seven (27) Infrared Search and Track (IRST) systems; forty (40) AIM–9X Block II Sidewinder tactical missiles; fifty (50) AIM–9X Block II Sidewinder Captive Air Training Missiles (CATMs); six (6) AIM–9X Block II Sidewinder Special Air Training Missiles (NATMs); four (4) AIM–9X Block II Sidewinder tactical guidance units; ten (10) AIM–9X Block II Sidewinder CATM guidance units; eighteen (18) KMU–572 JDAM Guidance Kits for GBU–54; twelve (12) Bomb MK–82 500LB, General Purpose; twelve (12) Bomb MK–82, Inert; twelve (12) GBU–53/B Small Diameter Bomb II (SDB II) All-Up Round (AUR); and eight (8) GBU–53/B SDB II Guided Test Vehicle (GTV). Also included are AN/APG–79 Active Electronically Scanned Array (AESA) radars; High Speed Video Network (HSVN) Digital Video Recorder (HDVR); AN/AVS–9 Night Vision Goggles (NVG); AN/AVS–11 Night Vision Cueing Device (NVCD); AN/ALE–47 Electronic Warfare Countermeasures Systems; AN/ARC–210 Communication System; AN/APX–111 Combined Interrogator Transponder; AN/ALE–55 Towed Decoys; launchers (LAU–115D/A, LAU–116B/A, LAU118A); Training Aids, Devices and Spares; Technical Data Engineering Change Proposals; Avionics Software Support; Joint Mission Planning System (JMPS); Data Transfer Unit (DTU); Accurate Navigation (ANAV) Global Positioning System (GPS) Navigation; KIV–78 Dual Channel Encryptor, Identification Friend or Foe (IFF); Cartridge Actuated Devices/Propellant Actuated Devices (CADs/PADs); Technical Publications; AN/PYQ–10C Simple Key Loader (SKL); Aircraft Spares; other support equipment; Aircraft Armament Equipment (AAE); aircraft ferry; transportation costs; other technical assistance; engineering technical assistance; contractor engineering technical support; logistics technical assistance; Repair of Repairables (RoR); aircrew and maintenance training; contractor logistics support; flight test services; Foreign Liaison Officer (FLO) support; auxiliary fuel tanks, system integration and testing; software development/integration; and other related elements of logistics and program support. For AIM–9X: containers; missile support and test equipment; provisioning; spare and repair parts; personnel training and training equipment; publications and technical data; and U.S. Government and contractor technical assistance and other related logistics support. For GBU–53/B SDB II and GBU–54: Detector Laser DSU–38A/B, Detector Laser DSU–38A(D–2)/B, FMU–139D/B Fuze, KMU–572(D–2)/B Trainer (JDAM), 40-inch Wing Release Lanyard; GBU–53/B SDB II Weapon Load Crew Trainers (WLCT); weapons containers; munitions support and test equipment; spares and repair parts; repair and return support; personnel training and training equipment; publications and technical documents; U.S. Government and contractor engineering, technical, and logistics support services; and other related elements of logistical and program support. The total estimated cost is $7.452 billion.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security of a friendly European nation that continues to be an important force for political stability and economic progress in Europe.

The proposed sale will improve Switzerland's capability to meet current and future threats. Switzerland currently operates the Boeing F/A–18C/D, but that aircraft is reaching end-of-life and will be replaced by the winner of Switzerland's New Fighter Aircraft competition, for which the F/A–18E/F is being considered. The primary missions of the aircraft and associated weapons will be policing the airspace above Switzerland and providing national

defense capabilities. Switzerland will have no difficulty absorbing these aircraft into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors will be The Boeing Company, St. Louis, MO; Northrop Grumman, Los Angeles, CA; Raytheon Company, El Segundo, CA; Raytheon Missile Systems Company, Tucson, AZ; General Electric, Lynn, MA; and The Boeing Company, St. Charles, MO. This proposal is being offered in the context of a competition. The purchaser typically requests offsets. Any offset agreement will be defined in negotiations between the purchaser and the contractor.

Implementation of this proposed sale will require the assignment of six (6) additional U.S. contractor representatives to Switzerland on an intermittent basis for a duration of the life of the case to support delivery of the F/A–18E/F Super Hornet aircraft and provide supply support management, inventory control, and equipment familiarization.

There will be no adverse impact on U.S. defense readiness as a result, of this proposed sale.

Transmittal No. 20–34 Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The F/A–18E/F Super Hornet is a single-seat and two-seat, twin engine, multi-mission fighter/attack aircraft that can operate from either aircraft carriers or land bases. The F/A–18E/F Super Hornet fills a variety of roles and provides air superiority, fighter escort, suppression of enemy air defenses, reconnaissance, forward air control, close and deep air support, and day and night strike missions.

a. The AN/APG–79 Active Electronically Scanned Array (AESA) Radar System provides the F/A–18E/F Super Hornet aircraft with all-weather, multi-mission capability for performing Air-to-Air and Air-to-Ground targeting and attack. Air-to-Air modes provide the capability for all-aspect target detection, long-range search and track, automatic target acquisition, and tracking of multiple targets. Air-to-Surface attack modes provide high-resolution ground mapping navigation, weapon delivery, and sensor cueing.

b. The AN/ALR–67(V)3 Electric Warfare Countermeasures Receiving Set provides the F/A–18E/F aircrew with radar threat warnings by detecting and evaluating friendly and hostile radar frequency threat emitters and providing identification and status information about the emitters to on-board Electronic Warfare (EW) equipment and the aircrew. The Operational Flight Program (OFP) and User Data Files (UDF) used in the AN/ALR–67(V)3 contain threat parametric data used to identify and establish priority of detected radar emitters.

c. The AN/ALE–47 Countermeasures Dispensing System is a threat-adaptive dispensing system that dispenses chaff, flares, and expendable jammers for self-protection against airborne and ground-based Radio Frequency (RF) and Infrared threats. The Operational Flight Program (OFP) and Mission Data Files (MDF) used in the AN/ALE–47 contain algorithms used to calculate the best defense against specific threats.

d. The AN/ALQ–214 is an advanced airborne Integrated Defensive Electronic Countermeasures (IDECM) programmable modular automated system capable of intercepting, identifying, processing received radar signals (pulsed and continuous) and applying an optimum countermeasures technique in the direction of the radar signal, thereby improving individual aircraft probability of survival from a variety of Surface-to-Air and Air-to-Air Radio Frequency (RF) threats. The system operates in a standalone or Electronic Warfare (EW) suite mode. In the EW suite mode, the AN/ALQ–214 operates in a fully coordinated mode with the towed dispensable decoy, Radar Warning Receiver (RWR), and the onboard radar in the F/A–18E/F Super Hornet in a coordinated, non-interference manner sharing information for enhanced information. The AN/ALQ–214 was designed to operate in a high-density Electromagnetic Hostile Environment with the ability to identify and counter a wide variety of multiple threats, including those with Doppler characteristics.

e. The AN/APX–111 Combined Interrogator/Transponder (CIT) with the Conformal Antenna System (CAS) is a complete MARK–XII identification system compatible with Identification Friend or Foe (IFF) Modes 1, 2, 3/A, C and 4 (secure). A single slide-in module that can be customized to the unique cryptographic functions for a specific country provides the systems secure mode capabilities. As a transponder, the CIT is capable or replying to interrogation modes 1, 2, 3/A C (altitude) and secure mode 4. The requirement is to upgrade Switzerland's Combined Interrogator Transponder (CIT) AN/APX–111 (V) IFF system software to implement Mode Select (Mode S) capabilities. Beginning in early 2005 EUROCONTROL mandated the civil community in Europe to transition to a Mode S only system and for all aircraft to be compliant by 2009. The Mode S Beacon System is a combined data link and Secondary Surveillance Radar (SSR) system that was standardized in 1985 by the International Civil Aviation Organization (ICAO). Mode S provides air surveillance using a data link with a permanent unique aircraft address. Selective Interrogation provides higher data integrity, reduced Radio Frequency (RF) interference levels, increased air traffic capacity, and adds air-to-ground data link.

f. The Joint Helmet Mounted Cueing System (JHMCS) is a modified HGU–55/P helmet that incorporates a visor-projected Heads-Up Display (HUD) to cue weapons and aircraft sensors to air and ground targets. In close combat, a pilot must currently align the aircraft to shoot at a target. JHMCS allows the pilot to simply look at a target to shoot. This system projects visual targeting and aircraft performance information on the back of the helmet's visor, enabling the pilot to monitor this information without interrupting his field of view through the cockpit canopy, the system uses a magnetic transmitter unit fixed to the pilot's seat and a magnetic field probe mounted on the helmet to define helmet pointing positioning. A Helmet Vehicle Interface (HVI) interacts with the aircraft system bus to provide signal generation for the helmet display. This provides significant improvement for close combat targeting and engagement.

g. The Joint Mission Planning System (JMPS) will provide mission planning capability for support of military aviation operations. It will also provide support for unit-level mission planning for all phases of military flight operations and have the capability to provide necessary mission data for the aircrew. JMPS will support the downloading of data to electronics data transfer devices for transfer to aircraft and weapon systems. A JMPS for a specific aircraft type will consist of basic planning tools called the Joint Mission Planning Environment (JMPE) mated with a Unique Planning Component (UPC) provided by the aircraft program. In addition, UPCs will be required for specific weapons, communication devices, and moving map displays. The JMPS will be tailored to the specific releasable configuration for the F/A–18E/F Super Hornet.

h. The AN/AVS–9 Night Vision Goggles (NVG) provide imagery sufficient for an aviator to complete

night time missions down to starlight and extreme low light conditions. The AN/AVS–9 is designed to satisfy the F/A–18E/F mission requirements for covert night combat, engagement, and support. The third generation light amplification tubes provide a high-performance, image-intensification system for optimized F/A–18E/F night flying at terrain-masking altitudes.

i. The AN/AVS–11 Night Vision Goggles (NVG) is capable of high resolution imaging. This capability allows reduced visibility weapon delivery. While the NVCD hardware is unclassified, this item requires Enhanced End Use Monitoring (EEUM).

j. The AN/ALE–55 Towed Decoy improves aircraft survivability by providing an enhanced, coordinated onboard/off-board countermeasure response to enemy threats.

k. The Multifunctional Informational Distribution System (MIDS) Joint Tactical Radio System (JTRS) a secure data and voice communication network using Link-16 architecture. The system provides enhanced situational awareness, positive identification of participants within the network, secure fighter-to-fighter connectivity, secure voice capability, and ARN–118 TACAN functionality. It provides three major functions: Air Control, Wide Area Surveillance, and Fighter-to-Fighter. The MIDS JTRS can be used to transfer data in Air-to-Air, Air-to-Surface, and Air-to-Ground scenarios. The MIDS Enhanced Interference Blanking Unit (EIBU) provides validation and verification of equipment and concept. EIBU enhances input/output signal capacity of the MIDS JTRS and addresses parts obsolescence.

l. LAU–127E/A Guided Missile Launchers designed to enable F/A–18E/F Super Hornet aircraft to carry and launch missiles. It provides the electrical and mechanical interface between the missile and launch aircraft as well as the two-way data transfer between missile and cockpit controls and displays to support preflight orientation and control circuits to prepare and launch the missile.

m. Accurate Navigation (ANAV) Global Positioning System (GPS) also includes Key Loading Installation and Facility Charges. The ANAV is a 24-channel SAASM based pulse-per-second GPS receiver built for next generation GPS technology.

n. The AN/ARC–210 Radio's Line-of-sight data transfer rates up to 80 kb/s in a 25 kHz channel creating high-speed communication of critical situational awareness information for increased mission effectiveness. Software that is reprogrammable in the field via Memory Loader/Verifier Software making flexible use for multiple missions. The AN/ARC–210 has embedded software with programmable cryptography for secure communications.

o. AN/PYQ–10(C) is the next generation of the currently fielded AN/CYZ–10 Data Transfer Device (DTD). The AN/PYQ–10(C) provides automated, secure and user-friendly methods for managing and distributing cryptographic key material, Signal Operating Instructions (SOI), and Electronic Protection data. This course introduces some of the basic components and activities associated with the AN/PYQ–10(C) in addition to hands-on training. Learners will become familiar with the security features of the SKL, practice the initial setup of the SKL, and will receive and distribute electronic keys using the SKL.

p. KIV–78 Dual Channel Encryptor Mode 4/Mode 5 Identify Friend or Foe (IFF) Crypto applique includes aircraft installs and initial spares, to ensure proper identification of aircraft during coalition efforts. The KIV–78 provides cryptographic and time-of-day services for a Mark XIIA (Mode 4 and Mode 5) IFF Combined Interrogator/Transponder (CIT), individual interrogator, and individual transponder.

q. Data Transfer Unit (DTU) with CRYPTO Type 1 and Ground Encryption Device (GED). The DTU (MU–1164(C)/A) has an embedded DAR–400EX and the GED (DI–12(C)/A) has an embedded DAR–400ES. Both versions of the DAR–400 are type 1 devices.

r. High Speed Video Network (HSVN) Digital Video Recorder (HDVR) with CRYPTO Type 1 and Ground Encryption Device (GED). The HDVR has an embedded DAR–400EX and the GED has an embedded DAR–400ES. Both versions of the DAR–400 are Type 1 devices.

s. The Advanced Targeting Forward Looking Infrared (ATFLIR)/or other targeting pod is a multi-sensor, electro-optical targeting pod incorporating infrared, low-light television camera, laser range finder/target designator, and laser spot tracker. It is used to provide navigation and targeting for military aircraft in adverse weather and using precision-guided weapons such as laser-guided bombs. It offers much greater target resolution and imagery accuracy than previous systems.

t. The Infrared Search and Track (IRST) is a long wave infrared targeting pod in an external fuel tank outer mold and carried on the centerline station. The IRST has an upgraded infrared receiver and processor to provide full system capability.

u. The Distributed Targeting Processor—Networked (DTP–N) will host the geo-location capability previously resident in the DTS, providing increased memory and speed, improving overall functionality. DTP–N enabled geo-registration and targeting enhancements, when used in conjunction with the advanced networking capabilities, will provide near real-time dissemination of actionable warfighting data thereby reducing kill chain times.

v. The M61A2 20MM Gun is a hydraulically, electrically or pneumatically driven, six-barrel, air-cooled, electrically fired Gatling-style rotary cannon which fires 20MM rounds at an extremely high rate. The M61 and its derivatives have been the principal cannon armament of United States military fixed-wing aircraft.

w. The F414–GE–400 Engine is a 22,000-pound class afterburning turbofan engine. The engine features an axial compressor with 3 fan stages and 7 high-pressure compressor stages, and 1 high-pressure and 1 low-pressure turbine stage. It incorporates advanced technology with the proven design base and features a Full Authority Digital Engine Control (FADEC) system—to provide the F/A–18E/F Super Hornet with a durable, reliable, and easy-to-maintain engine.

x. LAU–115D/A is a rail Launcher designed to enable F/A–18E/F Super Hornet aircraft to carry and launch missiles. The launcher is suspended from the bomb rack on wing stations. The LAU–127 launchers may be attached to the sides of the LAU–115 for carriage missiles.

y. LAU–116B/A Guided Missile Launchers designed to enable F/A–18E/F Super Hornet aircraft to carry and launch missiles. Two launchers, one left hand and one right hand, are installed in the underside of the aircraft fuselage at stations 4 and 6. The launchers are recessed in cavities within the aircraft fuselage, allowing the missiles to be semi recessed for aerodynamic purposes. Both versions of the LAU–116 are ejection launchers.

z. LAU–118A Guided Missile Launchers designed to enable F/A–18E/F Super Hornet aircraft to carry and launch missiles. It provides the electrical and mechanical interface between the missile and launch aircraft, as well as the two-way data transfer between missile and cockpit controls and displays to support preflight orientation and control circuits to prepare and launch the missile.

aa. Cartridge Actuated Devices (CADs) are designed for the F/A–18E/F Super Hornet as small explosive devices used

to eject stores from launched devices, actuate other explosive systems, or provide initiation for aircrew escape devices. Propellant Actuated Devices (PADs) are a tool or specialized mechanized device or gas generator system that is activated by a propellant or releases or directs work through a propellant charge. Weapons release, aircraft ejection, life support, and fire-suppression systems are some facets that rely heavily on CADs and PADs.

bb. Books and Other Publications includes flight manuals, technical manuals and support of technical data and updates, release and distribution of classified publications for the operation and/or maintenance of the F/A–18E/F aircraft or systems.

cc. Software provides for initial design and development of the Electronic Warfare Software suite which encompasses AN/ALQ–214, AN/ALE–47, ALE–55, ALR–67, as part of the System Configuration Set (SCS) builds.

dd. Technical Data provides for the F/A–18E/F post-production of classified test reports and other related documentation.

ee. Training Aide and Devices provides for upgraded classified lessons, hardware and installation for the Tactical Operational Flight Trainers (TOFT), Low Cost Trainers (LCT), Aircrew courseware and spares for delivery and installation of Systems Configuration Sets (SCS).

ff. The AIM–9X Block II SIDEWINDER Missile is a supersonic, short-range Air-to-Air (A/A) guided missile which employs a passive Infrared (IR) target acquisition system, proportional navigational guidance, and a closed-loop position servo Fin Actuator Unit (FAU). It represents a substantial increase in missile acquisition and kinematics performance over the AIM–9M and replaces the AIM–9X Block I Missile configuration. The missile includes a high off-boresight seeker, enhanced countermeasure rejection capability, low drag/high angle of attack airframe and the ability to integrate the Helmet Mounted Cueing System. The software algorithms are the most sensitive portion of the AIM–9X missile. The software continues to be modified via a pre-planned product improvement (P3I) program in order to improve its counter-countermeasure capabilities. No software source code or algorithms will be released.

gg. AIM–9X BLK II Captive Air Training Missile (CATM) is a flight certified inert mass simulator with a functioning Guidance Unit (GU). The CATM is the primary aircrew training device providing all pre-launch functions as well as realistic aerodynamic performance that equate to carrying a tactical missile. The CATM provides pilot training in aerial target acquisition and use of aircraft controls/displays.

hh. AIM–9X BLK II Special Air Training Missile (NATM) is a live flight test and training missile, with functioning GU and RM, designed for ignition and separation. The NATM is similar to the AIM–9X BLK II Tactical missile except the WDU–17/B Warhead is replaced with a Telemetry Section (TM) for streaming data to a ground station during flight and may be fired with or without a target. The telemetry cable is previously connected between the GU and Target Detector (TD). An Active Optical Target Detector (AOTD) and Telemetry cable is connected between the TD and TM. The Electronic Safety and Arming Device (ESAD) is replaced with an ESAD simulator.

ii. AIM–9X BLK II Tactical GU, WGU–57/B, provides the missile tracking, guidance, and control signals. The GU provides counter-countermeasures, improved reliability and maintainability over earlier Sidewinder models. Improvements include: (1) Upgrade/redesign to the Electronics Unit Circuit Card Assemblies, (2) a redesigned center section harnessing, and (3) a larger capacity missile battery.

jj. AIM–9X BLK II CATM GU, WGU–57/B, is identical to the tactical GU except the GU and Control Actuation System (CAS) batteries are inert and the software Captive. The software switch tells the missile processor that it is attached to a CATM and to ignore missile launch commands. The switch also signals software to not enter abort mode because there is no FAU connected to the GU.

kk. AIM–9X BLK II Multi-Purpose Training Missile (MPTM) is a ground training device used to train ground personnel in aircraft loading, sectionalization, maintenance, transportation, storage procedures, and techniques. The missile replicates external appearance and features of a tactical AIM–9X–2 missile. The MPTM will physically interface with loading equipment, maintenance equipment, launchers, and test equipment. The missile is explosively and electrically inert and is NOT flight certified.

ll. AIM–9X BLK II Dummy Air Training Missile (DATM) is used to train ground personnel in missile maintenance, loading, transportation, and storage procedures. All components are completely inert. The missile contains no programmable electrical components and is not approved for flight.

mm. AIM–9X BLK II Active Optical Target Detector (AOTD) is newly designed for Block II. The AOTD/Data Link (AOTD/DL) uses the latest laser technology allowing significant increases in sensitivity, aerosol performance, low altitude performance, and Pk (Probability of Kill). The AOTD/DL design includes a DL for 2-way platform communication. The AOTD/DL communicates with the GU over a serial interface which allows the GU to receive and transmit data so that a target position and status communication with a launching platform is possible during missile flight.

nn. The GBU–54 Laser Joint Direct Attack Munition (LJDAM) is a 500 pound JDAM which incorporates all the capabilities of the JDAM guidance tail kit and adds a precision laser guidance set. The LJDAM gives the weapon system an optional semi-active laser guidance in addition to the Inertial Navigation System/Global Positioning System (INS/GPS) guidance. This provides the optional capability to strike moving targets. The GBU–54 consists of a laser guidance set, KMU–572 warhead specific tail kit, and MK–82 bomb body.

oo. The GBU–53/B Small Diameter Bomb Increment II (SDB II) is a 250-lb class precision-guided, semi-autonomous, conventional, air-to-ground munition used to defeat moving targets through adverse weather from standoff range. The SDB II has deployable wings and fins and uses GPS/INS guidance, network-enabled datalink (Link-16 and UHF), and a multi-mode seeker (millimeter wave radar, imaging infrared) to autonomously search, acquire, track, and defeat targets. The SDB II employs a multi-effects warhead (Blast, Fragmentation, and ShapedCharge) for maximum lethality against armored and soft targets. The SDB II weapon system consists of the AUR weapon; a 4-place common carriage system; and mission planning system application.

pp. SDB II Guided Test Vehicles (GTV) is an SDB II configuration used for land or sea range-based testing of the SDB II weapon system. The GTV has common flight characteristics of an SDB II AUR, but in place of the multi-effects warhead is a Flight Termination, Tracking, and Telemetry (FTTT) subassembly that mirrors the AUR multi-effects warhead's size and mass properties, but provides safe flight termination, free flight tracking and telemetry of encrypted data from the GTV to the data receivers. The SDB II GTV can have either inert or live fuses. All other flight control, guidance, data-link, and seeker functions are representative of the SDB II AUR.

qq. SDB II Captive Carry Reliability Test (CCRT) vehicles are an SDB II configuration primarily used for reliability data collection during carriage. The CCRT has common characteristics of an SDB II AUR but with an inert warhead and fuze. The CCRT has an inert mass in place of the warhead that mimics the warhead's mass properties. The CCRT is a flight capable representative of the SDB II AUR but is not approved for release from any aircraft. Since all other flight control, guidance, data-link, and seeker functions are representative of the SDB II AUR, this configuration could be used for any purpose where an inert round without telemetry or termination capability would be useful.

2. The highest level of classification of defense articles, and services included in this potential sale is SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware or software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that Switzerland can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Switzerland.

[FR Doc. 2020–26543 Filed 12–1–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2020–HQ–0007]

Submission for OMB Review; Comment Request

AGENCY: United States Marine Corps, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 4, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and Omb Number: USMC Children, Youth and Teen Programs (CYTP) Registration Packet; NAVMC Forms 11720, 1750/4 and 1750/5; OMB Control Number 0703–0068.

Type of Request: Extension.

Number of Respondents: 112,000.

Responses per Respondent: 1.

Annual Responses: 112,000.

Average Burden per Response: 70 minutes.

Annual Burden Hours: 130,667.

Needs and Uses: The information collected on these forms is used by MFP and Inclusion Action Team (IAT) professionals for purposes of patron registration, to determine the general health status of patrons participating in CYTP activities and if necessary the appropriate accommodations for the patron for full enjoyment of CYTP services, and provides consent for information to be exchanged between MFP personnel and other designated individuals or organizations about a patron participating in MFP.

Affected Public: Business or other for-profit; individuals or households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 25, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–26532 Filed 12–1–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2020–HQ–0006]

Submission for OMB Review; Comment Request

AGENCY: Commander, Navy Installations Command, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 4, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Law Enforcement Officers Safety Act (LEOSA) Credential Program; SECNAV Form 5580/1; OMB Control Number 0703–0067.

Type of Request: Extension.

Number of Respondents: 900.

Responses per Respondent: 1.

Annual Responses: 900.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 450.

Needs and Uses: Department of the Navy and the U.S. Marine Corps are requesting Office of Management and Budget (OMB) approval of the information collection to verify and validate eligibility of separated and retired DON law enforcement officers to ship, transport, possess or receive Government-issued or private firearms or ammunition. This will also verify and

validate eligibility of separated, and retired DON law enforcement officers to receive DON endorsed law enforcement credentials, to include Law Enforcement Officers Safety Act (LEOSA) credentials.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 25, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–26529 Filed 12–1–20; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2020–HQ–0010]

Proposed Collection; Comment Request

AGENCY: United States Marine Corps, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the United States Marine Corp announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 1, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: The DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Office of the Department of the Navy Information Management Control Officer, 2000 Navy Pentagon, Rm. 4E563, Washington, DC 20350, Ms. Barbara Figueroa or call 703–614–7885.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and Omb Number: Navy Access Control Management System (NACMS) and the U.S. Marine Corps Biometric and Automated Access Control System (BAACS); the associated Form is SECNAV 5512/1 Department of the Navy Local Population ID Card/Base Access Pass Registration Form; OMB Control Number 0703–0061.

Needs and Uses: The information collection requirement is necessary to control physical access to Department of Defense (DoD), Department of the Navy (DON) or U.S. Marine Corps Installations/Units controlled information, installations, facilities, or areas over which DoD, DON or U.S. Marine Corps has security responsibilities by identifying or verifying an individual through the use of biometric databases and associated data processing/information services for designated populations for purposes of protecting U.S./Coalition/allied government/national security areas of responsibility and information; to issue badges, replace lost badges and retrieve passes upon separation; to maintain visitor statistics; collect information to adjudicate access to facility; and track the entry/exit of personnel.

Affected Public: Individuals or Households; Business or other for-profit; Not-for-profit institutions.

Annual Burden Hours: 816,667.

Number of Respondents: 4.9 million.

Responses per Respondent: 1.

Annual Responses: 4.9 million.

Average Burden per Response: 10 minutes.

Frequency: Daily.

Dated: November 25, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–26526 Filed 12–1–20; 8:45 am]

BILLING CODE 3810–FF–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Senior Executive Service Performance Review Board

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Notice of members of senior executive service performance review board.

SUMMARY: This notice announces the membership of the Defense Nuclear Facilities Safety Board (DNFSB) Senior Executive Service (SES) Performance Review Board (PRB).

DATES: These appointments were effective on October 20, 2020.

ADDRESSES: Send comments concerning this notice to: Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW, Suite 700, Washington, DC 20004–2001.

FOR FURTHER INFORMATION CONTACT: Vanessa D. Prout by telephone at (202) 694–7021 or by email at *VanessaP@dnfsb.gov.*

SUPPLEMENTARY INFORMATION: 5 U.S.C. 4314 (c)(1) through (5) requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more performance review boards. The PRB shall review and evaluate the initial summary rating of the senior executives' performance, the executives' responses, and the higher level officials' comments on the initial summary rating. In addition, the PRB will review and recommend executive performance bonuses and pay increases.

The DNFSB is a small, independent Federal agency; therefore, the members of the DNFSB SES Performance Review Board listed in this notice are drawn from the SES ranks of other agencies. The following persons comprise a standing roster to serve as members of the Defense Nuclear Facilities Safety Board SES Performance Review Board:

Dolline L. Hatchett, Director, Office of Safety Recommendations and Communications, National Transportation Safety Board

Jessica S. Bartlett, Regional Director, Federal Labor Relations Authority, Washington Regional Office

Catherine Haney, Assistant for Operations, Office of the Executive Director for Operations, Nuclear Regulation Commission

Authority: 5 U.S.C. 4314.

Dated: November 25, 2020.

Thomas A. Summers,

Acting Chairman.

[FR Doc. 2020–26531 Filed 12–1–20; 8:45 am]

BILLING CODE 3670–01–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2020–OCTAE–0176]

Request for Information on Expanding Work-Based Learning Opportunities for Youth

AGENCY: Office of Career, Technical, and Adult Education, Department of Education.

ACTION: Request for information.

SUMMARY: The U.S. Department of Education (Department) is requesting information on successful approaches for expanding work-based learning (WBL) opportunities for youth by working across Federal, State, and local education and employer systems. We will use this information to inform our implementation of the Carl D. Perkins Career and Technical Education Act of 2006, as amended by the Strengthening Career and Technical Education for the 21st Century Act (Perkins V).

DATES: We must receive your submission by January 13, 2021.

ADDRESSES: Submit your response to this request for information (RFI) through the Federal eRulemaking Portal. We will not accept submissions by postal mail, commercial mail, hand delivery, fax, or email. To ensure that we do not receive duplicate copies, please submit your comments only one time.

Federal eRulemaking Portal: Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the ''Help'' tab.

Privacy Note: The Department's policy for comments received from members of the public is to make these submissions available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available on the internet. We encourage, but do not require, that each respondent include his or her name, title, institution or affiliation, and the name, title, mailing and email addresses, and telephone number of a contact person for his or her institution or affiliation, if any.

This is a request for information only. This RFI is not a request for proposals (RFP) or a promise to issue an RFP or a notice inviting applications. This RFI does not commit the Department to contract for any supply or service whatsoever. Further, we are not seeking proposals and will not accept unsolicited proposals. The Department will not pay for any information or administrative costs that you may incur in responding to this RFI.

The documents and information submitted in response to this RFI become the property of the U.S. Government and will not be returned.

FOR FURTHER INFORMATION CONTACT: Kiawanta Hunter-Keiser, Office of Career, Technical, and Adult Education, U.S Department of Education, 400 Maryland Avenue SW, Room 11–119, Potomac Center Plaza, Washington, DC 20202–7240. Telephone: (202) 245–7724. Email: *Kiawanta.Hunter-Keiser@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Department awards approximately $1.3 billion annually for Career and Technical Education (CTE) State formula grants authorized under Perkins V. Perkins V assists States and outlying areas in expanding and improving CTE in secondary schools, technical schools, and community colleges. Each State uses program funds to support a variety of CTE programs and activities developed in accordance with its State plan.

The enactment of Perkins V in 2018 highlighted the provision of WBL [1] as an important strategy for preparing CTE students for further learning and careers. For example, the new law amended the definition of CTE to include WBL as a component (20 U.S.C. 2302(5)); directed States to identify in their State plans how individuals who are members of special populations [2] will be provided instruction and WBL opportunities in integrated settings that support competitive, integrated employment (20 U.S.C. 2342(d)(9)(E)); and permitted States to use State leadership funds to establish and expand WBL opportunities that are aligned to CTE programs and programs of study (20 U.S.C. 2344(b)(18)), as well as to facilitate the inclusion of WBL opportunities (including internships, externships, and simulated work environments) in CTE programs of study (20 U.S.C. 2344(b)(4)(C)).

At the local level, amendments made by the 2018 law required eligible recipients to describe in their applications for funds the WBL opportunities that they will provide to students participating in CTE programs and how they will work with representatives from employers to develop or expand WBL opportunities for CTE students (20 U.S.C. 2354(b)(6)). Providing a continuum of WBL opportunities, including simulated work environments, is also an authorized use of the funds by local recipients (20 U.S.C. 2355(b)(5)(E)). Importantly, the new law also included participation in WBL by secondary CTE concentrators as a new optional indicator of State performance (20 U.S.C. 2323(b)(2)(A)(iv)(I)(cc)). In the State plans submitted during summer 2020, 26 States selected this indicator as one

[1] Section 3(55) of Perkins V defines the term ''work-based learning'' to mean ''sustained interactions with industry or community professionals in real workplace settings, to the extent practicable, or simulated environments at an educational institution that foster in-depth, firsthand engagement with the tasks required in a given career field, that are aligned to curriculum and instruction.''

[2] Section 3(48) of Perkins V defines ''special populations'' to mean ''(A) individuals with disabilities; (B) individuals from economically disadvantaged families, including low-income youth and adults; (C) individuals preparing for non-traditional fields; (D) single parents, including single pregnant women; (E) out-of-workforce individuals; (F) English learners; (G) homeless individuals described in section 725 of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11434a); (H) youth who are in, or have aged out of, the foster care system; and (I) youth with a parent who—(i) is a member of the armed forces (as such term is defined in section 101(a)(4) of title 10, United States Code); and (ii) is on active duty (as such term is defined in section 101(d)(1) of such title).''

of their measures of secondary CTE program quality.[3]

The greater prominence of WBL in Perkins V and interest in expanding its availability comes at a time when participation in the labor market by youth is at a low point. Since 2000, there has been a precipitous drop in participation in the job market by adolescents ages 16 to 19 of all major races and ethnicities.[4] The labor force participation rate measures the percentage of individuals who are employed or who are seeking employment. During July, at the height of the summer, the labor force participation rate of 16- to 19-year-old youth declined from 62.9 percent in 1999 to 40.0 percent in 2020 (Table 1). This deep decline occurred among White youth, Black youth, Hispanic youth, and Asian youth. Summer job opportunities are particularly limited for low-income youth. The employment rate measures the percentage of individuals in the labor force who are employed. In July 2020, the employment rate of youth ages 16 to 19 from families with annual incomes of $20,000 or less was about half that of their peers from families with annual incomes of $150,000 or more (Table 2). Youth participation in the labor market throughout the year also has dropped significantly since 2000. The annual average rate of labor force participation among youth ages 16 to 19 fell from 52.0 percent in 1999 to 35.3 percent in 2019, with White youth, Black youth, Hispanic youth, and Asian youth all experiencing a decline (Table 3).

TABLE 1—PERCENTAGE OF YOUTH AGES 16 TO 19 PARTICIPATING IN THE LABOR FORCE DURING JULY

Year	All youth, ages 16–19	White youth, ages 16–19	Black youth, ages 16–19	Hispanic youth, ages 16–19	Asian youth, ages 16–19
1999	62.9	66.5	49.8	51.5	(*)
2000	61.8	65.6	50.2	51.4	37.2
2001	60.3	64.1	47.3	50.9	39.7
2002	57.5	61.1	42.7	48.9	43.9
2003	53.7	57.0	41.8	43.3	36.2
2004	53.6	57.1	41.8	45.0	33.1
2005	53.0	56.3	41.7	42.9	34.4
2006	53.5	56.9	43.1	44.9	32.6
2007	50.0	53.9	36.3	39.5	30.3
2008	49.6	53.2	37.7	41.5	30.0
2009	46.5	50.1	35.5	42.1	28.2
2010	42.6	46.0	30.8	36.8	31.9
2011	41.6	45.3	28.5	32.6	26.3
2012	43.4	45.9	37.0	37.9	23.0
2013	43.3	45.6	36.3	39.5	27.5
2014	42.3	45.3	32.0	36.2	27.9
2015	41.3	44.1	35.3	35.2	25.3
2016	43.2	46.0	34.4	35.3	24.9
2017	42.5	43.8	37.5	36.7	30.5
2018	43.0	45.4	36.3	37.9	25.1
2019	44.3	47.1	38.8	38.3	25.7
2020	40.0	42.4	35.9	34.2	20.9

Source: U.S. Bureau of Labor Statistics (BLS), Current Population Survey, not seasonally adjusted, 1999–2020. Retrieved by searching the BLS Data Finder 1.1 at *https://beta.bls.gov/dataQuery/search.*

* Data from 1999 on Asian youth ages 16 to 19 are not available.

TABLE 2—JULY 2020 EMPLOYMENT RATE OF YOUTH AGES 16 TO 19, BY ANNUAL FAMILY INCOME

Family income	July 2020 percentage employment rate
Under $20,000	18.9
$20,000–$39,999	24.3
$40,000–$59,999	32.4
$60,000–$74,999	33.3
$75,000–$99,999	35.4
$100,000–$149,999	37.9
+$150,000 and higher	40.3

Source: U.S. Census Bureau, Current Population Survey public use microdata, July 2020. Retrieved by searching the Census Bureau's MDAT tool at *https://data.census.gov/mdat/#/.*

[3] Perkins V State Plans approved by the Department can be found on the Department's website at *https://cte.ed.gov/grants/state-plan.*

[4] See, for example, Steven F. Hipple, ''Labor force participation: What has happened since the peak?,'' Monthly Labor Review, U.S. Bureau of Labor Statistics, September 2016, Retrieved from *https://doi.org/10.21916/mlr.2016.43.*

TABLE 3—ANNUAL AVERAGE PERCENTAGE OF YOUTH AGES 16 TO 19 PARTICIPATING IN THE LABOR FORCE

Year	All youth, Ages 16–19	White youth, ages 16–19	Black youth, ages 16–19	Hispanic youth, ages 16–19	Asian Youth, ages 16–19
1999	52.0	55.5	38.7	45.5	(*)
2000	52.0	55.5	39.4	46.3	35.8
2001	49.6	53.1	37.6	46.9	32.0
2002	47.4	50.5	36.0	44.0	33.3
2003	44.5	47.7	32.4	37.7	29.6
2004	43.9	47.1	31.4	38.2	28.4
2005	43.7	46.9	32.4	38.6	26.0
2006	43.7	46.7	34.0	38.3	25.1
2007	41.3	44.4	30.3	37.1	24.5
2008	40.2	43.1	29.4	36.9	24.9
2009	37.5	40.6	27.2	34.0	20.8
2010	34.9	37.7	25.5	30.9	22.0
2011	34.1	36.8	24.9	28.3	21.7
2012	34.3	36.9	26.9	30.9	20.1
2013	34.5	36.9	28.0	31.0	21.5
2014	34.0	36.2	27.2	30.3	21.0
2015	34.3	36.4	28.1	30.9	20.6
2016	35.2	37.4	29.0	31.2	21.2
2017	35.2	36.8	30.0	31.9	23.5
2018	35.1	37.2	30.5	32.5	19.6
2019	35.3	37.5	30.1	32.2	21.6

Source: U.S. Bureau of Labor Statistics, Current Population Survey, not seasonally adjusted, 1962–2019. Retrieved from the BLS Data Finder 1.1 at *https://beta.bls.gov/dataQuery/search.*

* Data from 1999 on Asian youth ages 16 to 19 are not available.

With the heightened interest in expanding WBL for CTE students occurring at the same time that participation in work by youth is waning, the Department is soliciting ideas and information from a broad array of stakeholders on strategies and approaches to expand WBL opportunities for primarily high school students ages 16 or 17. These opportunities may include, but are not limited to, paid internships, work study, cooperative education, apprenticeships, and pre-apprenticeships. Input on stabilizing and increasing WBL will also be critical to mitigate the potential short- and long-term impact of the pandemic on youth employment.

We are interested in learning about successful approaches to expanding WBL opportunities for youth from States, Tribes, State and local educational agencies, community-based and other nonprofit organizations, employers, industry associations, philanthropic organizations, faith-based organizations, researchers, and other interested individuals and entities. The public input provided in response to this notice will inform the deliberations of the Department on the implementation of Perkins V and the Department's consultation and coordination on activities related to federally supported youth employment initiatives with its partners in the implementation of the Workforce Innovation and Opportunity Act (Pub. L. 113–128), including the U.S. Departments of Labor and Health and Human Services.

In responding to the questions, please provide information about WBL in the context of both prior to and during the pandemic, as applicable.

Key Questions

1. What barriers have you seen in your State or community to helping 16- and 17-year-old students gain a WBL experience?

2. What WBL programs and strategies at the State or local level do you consider successful or can be efficiently brought to scale, including apprenticeship opportunities for high school and college students?

3. What role does the public elementary and secondary education system currently play in the development of career readiness for youth, and what role should it play?

4. How can we better align resources and administrative, regulatory, and statutory requirements to allow for greater collaboration between educators and private and nonprofit employers?

5. What do State and local workforce development boards established by Title I of the Workforce Innovation and Opportunity Act and their partners need to do to facilitate better leveraging Federal workforce dollars targeted at youth?

Detailed Questions

I. Successful Practices and Strategies

1. What Federal, State, and local programs or community collaborative efforts have led to expanded WBL for high school age students? What is the objective evidence of their success (*e.g.,* evidence from rigorous evaluations using, for instance, causal research designs)?

2. How might technology be leveraged to overcome geographic barriers to student participation in WBL in rural and other communities? Are there successful examples of virtual WBL?

3. What interventions, strategies, or practices would need to be included in a WBL program to increase the likelihood of its success?

4. What are ways to involve parents, students, and employers in planning and implementing WBL to help ensure that strategies will be successful in meeting their needs?

II. Public and Private Partnerships

1. Which State, local, nonprofit, and business partners have been involved in successful initiatives to expand WBL? Which partners should be involved in the future?

2. What role did or what role could philanthropic organizations play in supporting these types of initiatives?

3. How were the partnerships involved in those initiatives structured (*e.g.,* governance models, provision of services, shared funding, collaborative professional development)?

III. Outcomes, Data, and Evaluation Design

1. What existing data collection mechanisms can be harnessed to describe the characteristics of students and employers participating in WBL and to track performance outcomes of students who participate or do not participate in WBL?
2. What role, if any, do you believe a State's longitudinal data system should or could play in the development, tracking, and advancement of career readiness?
3. What do you see as the most predictive and helpful metrics and outcomes for success?
4. What are examples of some frameworks and protocols for sharing data efficiently across programs while meeting privacy and confidentiality requirements? What should be the specifications for additional frameworks or protocols for the effective sharing of information?
5. What are the best examples of schools and programs using data to track progress, inform course corrections, and evaluate program performance in WBL?
6. Would you consider participating in a Department-sponsored rigorous evaluation of an innovative WBL practice or strategy?

IV. Student Barriers

1. What are the legislative, regulatory, or other barriers that impede student participation in WBL? What barriers has the COVID–19 pandemic created?
2. Are the barriers created at the Federal, State, or local level?
3. Could the barriers be overcome through administrative action (*i.e.,* without changes to laws or regulations)? How and in what ways?
4. Would overcoming the barriers require changes in Federal or State laws? If so, what are those provisions of law and how would they need to be changed?
5. What are examples of schools or communities that have been successful in addressing transportation barriers to student participation in WBL?
6. What are the best assessment tools to identify, address, and overcome barriers to career readiness among students?
7. What strategies have been successful in expanding WBL opportunities for students from special populations, as well as students from major racial and ethnic groups?

V. Employer Barriers

1. What are the legislative, regulatory, or other barriers, such as liability concerns, that impede employer participation in WBL when hiring high school students ages 16 to 17? For students ages 18 to 19, including college students?
2. Are the barriers created at the Federal, State, or local level?
3. Could the barriers be overcome through administrative action (*i.e.,* without changes to laws or regulations)? How and in what ways?
4. Would overcoming the barriers require changes in Federal or State laws? If so, what are those provisions of law and how would they need to be changed?
5. Are there incentives that would help employers be more engaged with WBL in your community?

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 2324; 20 U.S.C. 3416.

Scott Stump,

Assistant Secretary for Career, Technical, and Adult Education.

[FR Doc. 2020–26483 Filed 12–1–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP21–244–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Amendment to Neg Rate Agmt (Southern 49811) to be effective 11/24/2020.
Filed Date: 11/24/20.
Accession Number: 20201124–5006.
Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–246–000.
Applicants: Colorado Interstate Gas Company, L.L.C.
Description: § 4(d) Rate Filing: LUF Quarterly Update to be effective 1/1/2021.
Filed Date: 11/24/20.
Accession Number: 20201124–5018
Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–247–000
Applicants: Young Gas Storage Company, Ltd.
Description: § 4(d) Rate Filing: Annual Fuel and L&U Update Filing 2021 to be effective 1/1/2021.
Filed Date: 11/24/20.
Accession Number: 20201124–5020.
Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–248–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Article 11.2(a) Inflation Adjustment Filing 2021 to be effective 1/1/2021.
Filed Date: 11/24/20.
Accession Number: 20201124–5022.
Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–249–000.
Applicants: Young Gas Storage Company, Ltd.
Description: § 4(d) Rate Filing: ATC Rate Adjustment (2020–2021) to be effective 12/1/2020.
Filed Date: 11/24/20.
Accession Number: 20201124–5024.
Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–250–000.
Applicants: Kinder Morgan Louisiana Pipeline LLC.
Description: § 4(d) Rate Filing: Modifications to Tariff Filing—Gas Quality to be effective 1/1/2021.
Filed Date: 11/24/20.
Accession Number: 20201124–5027.
Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–251–000.
Applicants: Kinder Morgan Louisiana Pipeline LLC.

Description: § 4(d) Rate Filing: Periodic Rate Adjustment to be effective 1/1/2021.

Filed Date: 11/24/20.

Accession Number: 20201124–5028.

Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–252–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Annual Fuel and L&U Filing 2021 to be effective 1/1/2021.

Filed Date: 11/24/20.

Accession Number: 20201124–5031.

Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–253–000.

Applicants: Colorado Interstate Gas Company, L.L.C.

Description: § 4(d) Rate Filing: ATC Update Filing—Young and Totem 2020–2021 to be effective 12/1/2020.

Filed Date: 11/24/20.

Accession Number: 20201124–5033.

Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–254–000.

Applicants: Kern River Gas Transmission Company.

Description: § 4(d) Rate Filing: 2020 Non-Leap Year Rates Filing to be effective 1/1/2021.

Filed Date: 11/24/20.

Accession Number: 20201124–5134.

Comments Due: 5 p.m. ET 12/7/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 25, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–26564 Filed 12–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR21–3–000]

Roaring Fork Midstream, LLC; Notice of Request for Temporary Waiver

Take notice that on November 24, 2020, Roaring Fork Midstream, LLC filed a petition seeking a temporary waiver of the tariff filing and reporting requirements of sections 6 and 20 of the Interstate Commerce Act and parts 341 and 357 of the Federal Energy Regulatory Commission's regulations (Commission), all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern time on December 28, 2020.

Dated: November 25, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–26565 Filed 12–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC21–26–000.

Applicants: Niagara Mohawk Power Corporation, New York Transco, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act, et al. of Niagara Mohawk Power Corporation, et al.

Filed Date: 11/24/20.

Accession Number: 20201124–5202.

Comments Due: 5 p.m. ET 12/15/20.

Docket Numbers: EC21–27–000.

Applicants: Neosho Ridge Wind, LLC, The Empire District Electric Company.

Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of Neosho Ridge Wind, LLC, et al.

Filed Date: 11/24/20

Accession Number: 20201124–5204.

Comments Due: 5 p.m. ET 12/15/20.

Docket Numbers: EC21–28–000.

Applicants: Niagara Mohawk Power Corporation, LS Power Grid New York Corporation I.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act, et al. of Niagara Mohawk Power Corporation, et al.

Filed Date: 11/24/20.

Accession Number: 20201124–5206.

Comments Due: 5 p.m. ET 12/15/20.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21–40–000.

Applicants: KCE TX 23, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of KCE TX 23, LLC.

Filed Date: 11/25/20.

Accession Number: 20201125–5121.

Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: EG21–41–000.

Applicants: KCE TX 11, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of KCE TX 11, LLC.

Filed Date: 11/25/20.
Accession Number: 20201125–5130.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: EG21–42–000.
Applicants: KCE TX 12, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of KCE TX 12, LLC.
Filed Date: 11/25/20.
Accession Number: 20201125–5131.
Comments Due: 5 p.m. ET 12/16/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER20–1736–002.
Applicants: Versant Power.
Description: Compliance filing: Order No. 864 Compliance Filing—Response to Staff Letter (ER20–1736–) to be effective N/A.
Filed Date: 11/25/20.
Accession Number: 20201125–5001.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER20–1739–001.
Applicants: American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.
Description: Compliance filing: ATSI Response to Deficiency Letter for Order No. 864 Compliance to be effective N/A.
Filed Date: 11/25/20.
Accession Number: 20201125–5013.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–482–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 1276R22 Evergy Metro NITSA NOA to be effective 2/1/2021.
Filed Date: 11/25/20.
Accession Number: 20201125–5007.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–483–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3620R1 Kansas City Board of Public Utilities NITSA NOA to be effective 9/1/2020.
Filed Date: 11/25/20.
Accession Number: 20201125–5009.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–484–000.
Applicants: Hardee Power Partners Limited.
Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing to be effective 11/26/2020.
Filed Date: 11/25/20.
Accession Number: 20201125–5011.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–485–000.
Applicants: Invenergy Energy Management LLC.
Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing to be effective 11/26/2020.
Filed Date: 11/25/20.
Accession Number: 20201125–5014.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–486–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 205 filing re: revisions to TCC credit requirements to be effective 12/31/9998.
Filed Date: 11/25/20.
Accession Number: 20201125–5015.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–487–000.
Applicants: Invenergy TN LLC.
Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing to be effective 11/26/2020.
Filed Date: 11/25/20.
Accession Number: 20201125–5016.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–488–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: OATT Administrative Filing to be effective 12/16/2016.
Filed Date: 11/25/20.
Accession Number: 20201125–5019.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–489–000.
Applicants: Duke Energy Progress, LLC.
Description: § 205(d) Rate Filing: DEP-Edenton Solar Reimbursement Agreement RS No. 375 to be effective 2/1/2021.
Filed Date: 11/25/20.
Accession Number: 20201125–5032.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–490–000.
Applicants: Midcontinent Independent System Operator Inc., Otter Tail Power Company.
Description: § 205(d) Rate Filing: 2020–11–25_SA 2690 OTP–MDU-NorthWestern Energy 1st Rev T–T (Big Stone) to be effective 10/29/2020.
Filed Date: 11/25/20.
Accession Number: 20201125–5040.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–491–000.
Applicants: DesertLink, LLC.
Description: § 205(d) Rate Filing: DesertLink Requests Authorization to Collect Regulatory Asset to be effective 1/25/2021.
Filed Date: 11/25/20.
Accession Number: 20201125–5043.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–492–000.
Applicants: Massachusetts Electric Company.
Description: § 205(d) Rate Filing: 2020 Rate Update Filing for Massachusetts Electric Borderline Sales Agreement to be effective 11/1/2019.
Filed Date: 11/25/20.
Accession Number: 20201125–5044.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–493–000.
Applicants: Duke Energy Florida, LLC.
Description: § 205(d) Rate Filing: DEF–DEF E&P Agreement RS No. 331 to be effective 11/26/2020.
Filed Date: 11/25/20.
Accession Number: 20201125–5045.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–494–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original WMPA 5856; Queue No. AF2–379 to be effective 10/27/2020.
Filed Date: 11/25/20.
Accession Number: 20201125–5046.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–495–000.
Applicants: Basin Electric Power Cooperative.
Description: § 205(d) Rate Filing: Basin Electric Submission of Wholesale Power Contract to be effective 2/1/2021.
Filed Date: 11/25/20.
Accession Number: 20201125–5055.
Comments Due: 5 p.m. ET 12/16/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 25, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–26567 Filed 12–1–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0619; FRL–10017–85–OAR]

Clean Air Act Advisory Committee (CAAAC): Notice of Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the Environmental Protection Agency (EPA) is announcing a public meeting of the Clean Air Act Advisory Committee (CAAAC) to be conducted via remote/virtual participation only. Due to unforeseen administrative circumstances, EPA is announcing this meeting with less than 15 calendar days' notice. The EPA renewed the CAAAC charter on November 19, 2020 to provide independent advice and counsel to EPA on policy issues associated with implementation of the Clean Air Act of 1990. The Committee advises EPA on economic, environmental, technical, scientific and enforcement policy issues.

DATES: Pursuant to 5 U.S.C. App. 2 Section 10(a)(2), notice is hereby given that the CAAAC will hold its next public meeting remote/virtually on Tuesday, December 8th and Wednesday, December 9th from 12:45 p.m. to 5:15 p.m. (EST). Members of the public may register to listen to the meeting or provide comments by emailing at *caaac@epa.gov* by 5 p.m. (EST) December 4, 2020.

FOR FURTHER INFORMATION CONTACT: Shanika Whitehurst, Designated Federal Official, Clean Air Act Advisory Committee (6103A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–564–8235; email address: *whitehurst.shanika@epa.gov*. Additional information about this meeting, the CAAAC, and its subcommittees and workgroups can be found on the CAAAC website: *http://www.epa.gov/caaac/*.

SUPPLEMENTARY INFORMATION: The committee agenda and any documents prepared for the meeting will be publicly available on the CAAAC website at *http://www.epa.gov/caaac/* prior to the meeting. Thereafter, these documents, together with CAAAC meeting minutes, will be available on the CAAAC website or by contacting the Office of Air and Radiation Docket and requesting information under docket EPA–HQ–OAR–2020–0619. The docket office can be reached by email at: *a-and-r-Docket@epa.gov* or FAX: 202–566–9744.

For information on access or services for individuals with disabilities, please contact Lorraine Reddick at *reddick.lorraine@epa.gov,* preferably at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

Dated: November 27, 2020.

Catrice Jefferson,

Acting Director,Office of Air Policy and Program Support.

[FR Doc. 2020–26584 Filed 12–1–20; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Sunshine Act Meeting; Farm Credit Administration Board

AGENCY: Farm Credit Administration.

ACTION: Notice, regular meeting.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act, of the forthcoming regular meeting of the Farm Credit Administration Board.

DATE AND TIME: The regular meeting of the Board will be held December 10, 2020, from 9:00 a.m. until such time as the Board may conclude its business. *Note: Because of the COVID–19 pandemic, we will conduct the board meeting virtually. If you would like to observe the open portion of the virtual meeting, see instructions below for board meeting visitors.*

Attendance: To observe the open portion of the virtual meeting, go to FCA.gov, select ''Newsroom,'' then ''Events.'' There you will find a description of the meeting and a link to ''Instructions for board meeting visitors.'' See **SUPPLEMENTARY INFORMATION** for further information about attendance requests.

Contact: Dale Aultman, Secretary to the Farm Credit Administration Board (703) 883–4009. TTY is (703) 883–4056.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public, and parts will be closed. If you wish to observe the open portion, follow the instructions above in the ''Attendance'' section at least 24 hours before the meeting. If you need assistance for accessibility reasons or if you have any questions, contact Dale Aultman, Secretary to the Farm Credit Administration Board, at (703) 883–4009. The matters to be considered at the meeting are as follows:

Open Session

A. Approval of Minutes

- November 19, 2020

B. Reports

- Quarterly Report on Economic Conditions and FCS Conditions and Performance
- Semi-Annual Report on Office of Examination Operations

New Business

- Extension of No Action Until Investment Eligibility Rule's Effective Date

Closed Session

- Office of Examination Quarterly Report [1]

Dated: November 30, 2020.

Dale Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2020–26658 Filed 11–30–20; 4:15 pm]

BILLING CODE 6705–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Revision of Information Collection; Survey of Household Use of Banking and Financial Services; Comment Request (3064–NEW)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the survey collection instrument for its seventh biennial survey of households, which has been renamed the Survey of Household Use of Banking and Financial Services ''Household Survey''). This survey was previously named the FDIC National Survey of Unbanked and Underbanked Households and was assigned OMB Control No. 3064–0167. FDIC is seeking a new OMB Control Number for this version of the survey. The 2021 Household Survey is scheduled to be conducted in partnership with the U.S. Census Bureau as a supplement to its June 2021 Current Population Survey (CPS). The survey collects information on U.S. households' use of bank accounts, other transaction accounts including prepaid cards and online payment services, nonbank financial transaction services, and bank and nonbank credit. The results of these biennial surveys will be published in the FDIC's *How America Banks* reports which help inform policymakers, bankers, and researchers about how households use, or don't use, the banking system.

DATES: Comments must be submitted on or before February 1, 2021.

[1] Closed session is exempt pursuant to 5 U.S.C. Section 552b(c)(8) and (9).

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Agency website: https://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza, Regulatory Counsel, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to ''Household Survey''. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Regulatory Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: The FDIC is requesting OMB approval for the following collection of information:

Title: Survey of Household Use of Banking and Financial Services.

OMB Number: 3064–NEW.

Frequency of Response: Once.

Affected Public: Individuals residing in U.S. Households.

Estimated Number of Respondents: 40,000.

Average time per response: 9 minutes (0.15 hours) per respondent.

Estimated Total Annual Burden: 6,000 hours.

General Description of Collection: The Survey of Household Use of Banking and Financial Services (Household Survey) supports the FDIC's mission of maintaining public confidence in the U.S. financial system. The Household Survey is also a key component of the FDIC's compliance with a Congressional mandate contained in section 7 of the Federal Deposit Insurance Reform Conforming Amendments Act of 2005 (Reform Act) (Pub. L. 109–173), which calls for the FDIC to conduct ongoing surveys ''on efforts by insured depository institutions to bring those individuals and families who have rarely, if ever, held a checking account, a savings account or other type of transaction or check cashing account at an insured depository institution (hereafter in this section referred to as the 'unbanked') into the conventional finance system.'' Section 7 further instructs the FDIC to consider several factors in its conduct of the surveys, including: (1) ''what cultural, language and identification issues as well as transaction costs appear to most prevent 'unbanked' individuals from establishing conventional accounts''; and (2) ''what is a fair estimate of the size and worth of the ''unbanked'' market in the United States.''

The Household Survey collects information on bank account ownership which provides a factual basis for measuring the number and percentage of households that are unbanked. The Household Survey is the only population-representative survey conducted at the national level that provides state-level estimates of the size and characteristics of unbanked households for all 50 states and the District of Columbia. The Household Survey also collects information from unbanked households about the reasons that they do not have a bank account and their interest in having a bank account. Increasingly, financial products and services are provided by nonbanks, many through the use of a mobile phone app. Households are selecting different combinations of bank and nonbank financial products and services to meet their core banking needs. Consequently, the Household Survey has broadened its focus to include a wide range of bank and nonbank financial products and services and to collect information on whether and how households are using these in combination.

To obtain this information, the FDIC partners with the U.S. Census Bureau, which administers the Household Survey supplement (FDIC Supplement) to households that participate in the CPS. The supplement has been administered every other year since January 2009. The previous survey questionnaires and survey results can be accessed through the following link: *http://www.economicinclusion.gov/surveys/.*

Consistent with the statutory mandate to conduct the surveys on an ongoing basis, the FDIC already has in place arrangements for conducting the seventh Household Survey as a supplement to the June 2021 CPS.

Prior to finalizing the 2021 survey questionnaire, the FDIC seeks to solicit public comment on whether changes to the existing instrument are desirable and, if so, to what extent. It should be noted that, as a supplement of the CPS survey, the Household Survey needs to adhere to specific parameters that include limits in the length and sensitivity of the questions that can be asked of CPS respondents. Interested members of the public may obtain a copy of the proposed survey questionnaire on the following web page: *https://www.fdic.gov/regulations/laws/federal/2020/2021-survey-of-household-use-of-banking-and-financial-services.pdf.*

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on November 27, 2020.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2020–26572 Filed 12–1–20; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Transitions of Care From Pediatric to Adult Services for Children With Special Healthcare Needs

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Transitions of Care from Pediatric to Adult Services for Children with Special Healthcare Needs,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before January 4, 2021.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Transitions of Care from Pediatric to Adult Services for Children with Special Healthcare Needs.* AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Transitions of Care from Pediatric to Adult Services for Children with Special Healthcare Needs,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/transitions-care-pediatric-adult/protocol.*

This is to notify the public that the EPC Program would find the following information on *Transitions of Care from Pediatric to Adult Services for Children with Special Healthcare Needs* helpful:

■ A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

■ *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

■ *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

■ Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

- *KQ1:* What are the effectiveness, comparative effectiveness, harms, and costs of care interventions for transition from pediatric to adult medical care services, including primary care, for children with special healthcare needs and their families/caregivers?
  - *KQ1a:* How do outcomes vary by intervention characteristics or components?
  - *KQ1b:* How do outcomes vary by patient/caregiver or provider characteristics or setting?
  - *KQ1c:* What are the barriers and facilitators to effective transitions?
  - *KQ1d:* What are the gaps in evidence for the effectiveness of the interventions?
- *KQ2:* What are the effectiveness, comparative effectiveness, harms, and costs of implementation strategies for care interventions for transition, including provider-related training?
  - *KQ2a:* How do outcomes vary by intervention characteristics or components?
  - *KQ2b:* How do outcomes vary by patient/caregiver or provider characteristics or setting?
  - *KQ2c:* What are the barriers and facilitators to effective implementation?
  - *KQ2d:* What are the gaps in evidence for the effectiveness of the interventions?
- *KQ3:* What is the effectiveness, comparative effectiveness, harms, and costs of tools to facilitate communication between pediatric and adult providers for care transitions from pediatric to adult medical care for children with special healthcare needs and their families/caregivers?
  - *KQ3a:* How do outcomes vary by intervention characteristics or components?
  - *KQ3b:* How do outcomes vary by patient/caregiver or provider characteristics or setting?
  - *KQ3c:* What are the barriers and facilitators to effective tools to facilitate communication?
  - *KQ3d:* What are the gaps in evidence for the effectiveness of the interventions?

Contextual Questions

In addition to the identified key questions, the report will include a mixed-methods evaluation of the contexts in which interventions for transitioning children with special healthcare needs from pediatric to adult services are developed and used. Contextual questions to be evaluated include:

1. How is effectiveness defined and measured for transitions of care from pediatric to adult services for children with special healthcare needs?
2. What transition care training and other implementation strategies are available to prepare pediatric medical providers (*e.g.,* pediatricians and other specialists) and adult medical providers (*e.g.,* primary care providers, nurse practitioners, physician assistants) for transitioning children with special healthcare needs to adult care?
3. What training is available for linguistic- and culturally competent care?
4. What transition care training and other implementation strategies are available to prepare pediatric patients and their families for transitioning children with special healthcare needs to adult care?

5. What care interventions including primary care have been used for transition from pediatric to adult medical care for children with special healthcare needs?

6. What strategies have been proposed to increase availability of adult care providers for people transitioning from pediatric to adult care?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)

PICOT	KQ1: Benefits and harms of care intervention	KQ2: Implementation strategies	KQ3: Communication tools
Population	Adolescents and young adults (diagnosed with cancer or other special healthcare condition before 21 years old) with a chronic physical or mental illness or physical, intellectual, or developmental disability, also including parents and/or care givers. *Patient subgroups:* Disease condition (including cancer), age of diagnosis, sex/sexual orientation, race/ethnicity, religion, socioeconomic status, adverse childhood events. *Provider subgroups:* Age, sex, race/ethnicity, education, socioeconomic status, specialty, care setting.	Multi-disciplinary care providers (*e.g.,* primary care/family medicine physicians, specialty care physicians, nurse practitioners, physician assistant, etc.) caring for adolescents and young adults with a special healthcare need. *Patient subgroups:* Disease condition (including cancer), age of diagnosis, sex/sexual orientation, race/ethnicity, religion, socioeconomic status, adverse childhood events. *Provider subgroups:* Age, sex, race/ethnicity, education, socioeconomic status, specialty, care setting.	Multi-disciplinary care providers (*e.g.,* primary care/family medicine physicians, specialty care physicians, nurse practitioners, physician assistant, etc.) providers caring for adolescents and young adults with a special need. *Patient subgroups:* Disease condition (including cancer), age of diagnosis, sex/sexual orientation, race/ethnicity, religion, socioeconomic status, adverse childhood events. *Provider subgroups:* Age, sex, race/ethnicity, education, socioeconomic status, specialty, care setting.
Intervention	Intervention related to the care transition from pediatric to adult medical care (*e.g.*, any single or multi-component intervention that addresses the Six Core Elements of healthcare transition such as educational materials, patient care documents, processes, etc. There are not widely established neat packages of intervention components; interventions vary widely in their components, structure, and processes.). No healthcare transition intervention is explicitly excluded. However, transition interventions that address the full spectrum of transition to adult life, such as transition to independent living from foster care or among people with developmental disabilities, will be excluded.	Implementation strategies, including training (*e.g.,* any single or multi-component intervention that addresses implementing the Six Core Elements of healthcare transition such as trainings).	Tools for provider communication (*e.g.,* any single or multi-component intervention that addresses communication that supports the Six Core Elements of healthcare transition such as patient care documents).
Comparators	Comparator required, but no exclusion based on comparator type.	Comparator required, but no exclusion based on comparator type.	Comparator required, but no exclusion based on comparator type.
Outcomes	○ Transition readiness (*e.g.*, patient, family, provider, and system level). ○ Quality of life. ○ Mortality. ○ Morbidity. ○ Disease-specific clinical outcomes. ○ Wellness visits/screenings (*e.g.*, depression, anxiety, STIs, other risk and resiliency factors such as alcohol use, substance abuse, violence). ○ Treatment or care adherence. ○ Engagement in care (*e.g.*, no shows, time between provider, satisfaction, loss to follow-up, time between leaving pediatric setting to going to adult). ○ Satisfaction (patient and family).; ○ Family caregiver outcomes. ○ Harms. ○ Unintended consequences (*e.g.,* ethics of transition). ○ Psychosocial (*e.g.*, social-emotional, mental health, etc.). ○ Insurance. ○ Cost. ○ Resource utilization (ER visit, hospitalization, length of stay).	○ Intervention. ▪ Adoption. ▪ Fidelity. ▪ Sustainability. ▪ Feasibility. ▪ Acceptability. ○ Satisfaction (physician and other formal caregiver). ○ Quality of life. ○ Mortality. ○ Morbidity. ○ Disease-specific clinical outcomes. ○ Family Caregiver outcomes. ○ Harms. ○ Unintended consequences (*e.g.*, ethics of transition. ○ Cost of implementation. ○ Insurance.	○ Transition readiness. ○ Quality of life. ○ Mortality. ○ Morbidity. ○ Disease-specific clinical outcomes. ○ Treatment or care adherence. ○ Engagement in care (*e.g.*, no shows, time between providers, satisfaction, loss to follow-up, time between leaving pediatric setting to going to adult). ○ Satisfaction (patient and family). ○ Family Caregiver outcomes. ○ Harms. ○ Unintended consequences (*e.g.*, ethics of transition). ○ Insurance. ○ Cost. ○ Resource utilization (ER visit, hospitalization, length of stay).
Timing	At least 6 months post transition for tests of interventions. No exclusions for qualitative or mixed studies for barriers and facilitators subquestion.	At least 6 months for tests of interventions. No exclusions for qualitative or mixed studies for barriers and facilitators subquestion.	At least 6 months for tests of interventions. No exclusions for qualitative or mixed studies for barriers and facilitators subquestion.
Setting	All settings (*e.g.*, primary care, specialty care, schools, rural, resource limited settings, and telehealth).	All settings (*e.g.*, primary care, specialty care, schools, rural, resource limited settings, and telehealth).	All settings (*e.g.*, primary care, specialty care, schools, rural, resource limited settings, and telehealth).

Dated: November 27, 2020.

Marquita Cullom,

Associate Director.

[FR Doc. 2020–26569 Filed 12–1–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Living Systematic Review on Plant-Based Treatment for Chronic Pain

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our *Living Systematic Review on Plant-Based Treatment for Chronic Pain,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before January 4, 2021.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for a *Living Systematic Review on Plant-Based Treatment for Chronic Pain.* AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Plant-Based Treatment for Chronic Pain,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/plant-based-chronic-pain-treatment/protocol.*

This is to notify the public that the EPC Program would find the following information on Plant-Based Treatment for Chronic Pain helpful:

■ A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

■ *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

■ *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

■ Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

1. In adults with chronic pain, what are the benefits of cannabinoids?
2. In adults with chronic pain, what are the harms of cannabinoids?
3. In adults with chronic pain, what are the benefits of kratom or other plant-based substances for treatment of chronic pain?
4. In adults with chronic pain, what are the harms of kratom or other plant-based substances for treatment of chronic pain?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)

PICOTS element	Inclusion criteria	Exclusion criteria
Population	*All KQs:* Adults (including pregnant or breastfeeding women) 18 years and older with chronic pain (≤12 weeks or pain persisting past the time for normal tissue healing). See categorization of specifically included pain populations below.	*All KQs:* Children and adolescents <18 years old; adults with acute or subacute pain; patients at end of life or in palliative care (*e.g.,* with late stage cancer-related pain).
Interventions	*KQs 1 and 2:* Cannabinoids (including synthetics) using different delivery mechanisms such as oral, buccal, inhalational, topical, or other administration routes. *KQs 3 and 4:* Kratom or other plant-based substances; co-use of kratom or other plant-based substances and opioids. *All KQs:* Co-use of other drugs for pain.	*All KQs:* Non-plant-based interventions, capsaicin, herbal supplements.
Comparators	*All KQs:* Any comparator, or usual care	*All KQs:* No comparison.

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)—Continued

PICOTS element	Inclusion criteria	Exclusion criteria
Outcomes	*All KQs:* Primary efficacy outcomes (*i.e.,* pain, function, disability, pain interference); harms and adverse effects (*e.g.,* dizziness, nausea, sedation, development of cannabis use disorder); secondary outcomes (*i.e.,* psychological distress including depression and anxiety, quality of life, opioid use, sleep quality, sleep disturbance, health care utilization).	*All KQs:* Other outcomes.
Time of follow-up	*All KQs:* short term (1 to <6 months), intermediate term (6 to <12 months), long term (≥1 year).	*All KQs:* studies with <1-month of treatment or followup after treatment.
Setting	*All KQs:* Any nonhospital setting or setting of self-directed care.	*All KQs:* Hospital care, hospice care, emergency department care.
Study design	*All KQs:* RCTs; observational studies with a concurrent control group for harms, and to fill gaps in the evidence for benefits.	*All KQs:* Other study designs.

Abbreviations: RCT = randomized controlled trial.

Dated: November 27, 2020.

Marquita Cullom,

Associate Director.

[FR Doc. 2020–26570 Filed 12–1–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)-RFA–PS–21–003, PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices; and RFA–PS–21–004, Implementing and Evaluating a Data-to-Care Rx Strategy.

Date: February 23–24, 2021.

Time: 10:00 a.m.–5:00 p.m., EST.

Place: Teleconference, Centers for Disease Control and Prevention, Room 1080, 8 Corporate Square Boulevard, Atlanta, Georgia 30329–4027.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop US8–1, Atlanta, Georgia 30329–4027, (404) 718–8833, *GAnderson@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020–26558 Filed 12–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2020–0121]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. The meeting will be webcast live via the World Wide Web.

DATES: The meeting will be held on December 1, 2020 from 2:00 p.m. to 5:00 p.m., EST (times subject to change).

Written comments must be received on or before December 3, 2020.

ADDRESSES: For more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

You may submit comments, identified by Docket No. CDC–2020–0121 by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket No. CDC–2020–0121, c/o Attn: November 23, 2020 ACIP Meeting, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, GA 30329–4027.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS–H24–8, Atlanta, GA 30329–4027; Telephone: 404–639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is

being given for this meeting due to the exceptional circumstances of the COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency. A notice of this ACIP meeting has also been posted on CDC's ACIP website at: *http://www.cdc.gov/vaccines/acip/index.html.* In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

Matters to be Considered: The agenda will include discussions on COVID–19 vaccine allocation. A recommendation vote is scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.*

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials are part of the public record and are subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket. CDC does not accept comment by email.

Written Public Comment: Written comments must be received on or before December 3, 2020.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the December 1, 2020 ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EST, November 30, 2020 according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by 12:00 p.m., EST, December 1, 2020. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020–26587 Filed 11–30–20; 11:15 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1987–P–0074]

Canned Pacific Salmon Deviating From Identity Standard; Amendment of Temporary Marketing Permit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending Bumble Bee Seafoods Inc.'s temporary permit to market test canned skinless and boneless chunk salmon packed in water that contains sodium tripolyphosphate to inhibit protein curd formation during retorting. The temporary permit is amended to add an additional manufacturing location. This amendment will allow the applicant to continue to test market the test product and collect data on consumer acceptance of the test product.

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 13, 1987 (52 FR 26186), we issued a notice announcing that we had issued a temporary permit to Bumble Bee Seafoods, Inc., San Diego, CA 92123, to market test products identified as canned skinless and boneless chunk salmon packed in water and containing added sodium tripolyphosphate to inhibit protein curd formation during retorting. The permit allowed for the test product to be manufactured at a plant located in Petersburg, AK. We issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for canned Pacific salmon in 21 CFR 161.170, which were issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

In the **Federal Register** of April 8, 1988 (53 FR 11710), we issued a notice announcing that we had amended the temporary permit to permit the test product be manufactured at one additional plant, Chugach Alaska Fisheries, Inc., Ocean Dock Rd., Cordova, AK 99574.

In the **Federal Register** of September 6, 1988 (53 FR 34354), we issued another notice announcing that we were extending the expiration date of the permit to either the effective date of a

final rule for any proposal to amend the standard of identity for canned Pacific salmon that may result from the National Food Processors Association's petition, submitted on behalf of Bumble Bee Seafoods, Inc., and other salmon packers holding temporary permits, or 30 days after termination of such proposal.

In the **Federal Register** of April 24, 2020 (85 FR 23047), we issued a notice announcing that we amended the temporary permit to allow for the canned skinless and boneless chunk salmon packed in water with or without sodium tripolyphosphate and to allow the test product to be manufactured only at one plant, Pataya Food Industries Ltd., located at 90/6 Moo 7, Settakit Road, Tambol Tarsai, Amphur Maung, Samutsakorn 74000, Thailand.

Under our regulations at 21 CFR 130.17(f), we are amending the temporary permit issued to Bumble Bee Seafoods, Inc., to allow the test product to be manufactured at an additional plant, RS Cannery Company Limited, located at 255/1 Industrial Soi 3, Bangpoo Industrial Estate, Samutprakarn 10280, Thailand. All other conditions and terms of this permit remain the same.

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26533 Filed 12–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–1119; FDA–2010–N–0622; FDA–2011–N–0016; FDA–2009–N–0501; and FDA–2019–N–6098]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified and Thermally Processed Low-Acid Foods	0910–0037	10/31/2023
Color Additive Certification Requests and Recordkeeping	0910–0216	10/31/2023
Recordkeeping and Records Access Requirements for Food Facilities	0910–0560	10/31/2023
Reporting and Recordkeeping Requirements for Reportable Food	0910–0643	10/31/2023
Focus Groups as Used by the Food and Drug Administration	0910–0497	11/30/2023

Dated: November 25, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26571 Filed 12–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0190]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our infant formula regulations, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping. The notice also invites comment on electronic Form FDA 3978 that allows manufacturers of infant formula to submit reports and notifications in a standardized format.

DATES: Submit either electronic or written comments on the collection of information by February 1, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 1, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 1, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any

confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2010–N–0190 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Infant Formula Requirements—21 CFR Parts 106 and 107

OMB Control Number 0910–0256—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (FD&C Act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify us when infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. We have issued regulations to implement the FD&C Act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). We also regulate the labeling of infant formula under the authority of section 403 of the FD&C Act (21 U.S.C. 343). Under our labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. Failure to comply with any of the applicable labeling regulations will render an infant formula misbranded under section 403 of the FD&C Act. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately.

While the infant formula regulations help ensure the consistent production of safe and nutritionally adequate infant formulas for healthy term infants, they apply with one narrow exception. Section 412(h)(1) of the FD&C Act exempts an infant formula represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of subsections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as ''exempt infant formulas.'' Section 412(h)(2) of the FD&C Act authorizes us to establish terms and conditions for the exemption of an infant formula from the requirements of subsections 412(a), (b), and (c) of the FD&C Act.

In support of exempt infant formulas, we have issued the agency guidance document entitled, ''Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports.'' The guidance document includes our recommendation that manufacturers of exempt infant formulas follow, to the extent practicable, subparts A, B, C, D, and F of 21 CFR part 106, and is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exempt-infant-formula-production.*

We have also developed electronic Form FDA 3978 (Infant Formula Tracking System (IFTRACK)) so that infant formula manufacturers may electronically submit reports and notifications in a standardized format to FDA. However, manufacturers that prefer to submit paper submissions in a format of their own choosing will still have the option to do so. Form FDA 3978 prompts a respondent to include reports and notifications in a standard electronic format and helps the respondent organize their submission to include only the information needed for our review. Screenshots of Form FDA 3978 and instructions are available at *http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.*

Description of Respondents: Respondents to this information collection are manufacturers of infant formula.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C act or 21 CFR	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reports; Section 412(d) of the FD&C Act	5	13	65	10	650
Notifications; § 106.120(b)	1	1	1	4	4
Reports for exempt infant formula; § 107.50(b)(3) and (4).	3	2	6	4	24
Notifications for exempt infant formula; § 107.50(e)(2)	1	1	1	4	4
Requirements for quality factors— growth monitoring study exemption; § 106.96(c).	4	9	36	20	720
Requirements for quality factors—PER exemption; § 106.96(g).	1	34	34	12	408
New infant formula registration; § 106.110	4	9	36	0.50 (30 mins.)	18
New infant formula submission; § 106.120	4	9	36	10	360
Total					2,188

[1] There are no capital or operating and maintenance costs associated with the information collection.

Based on a review of the information collection, we have adjusted our burden estimate to correct a nominal calculation error. This reflects a decrease of 62 annual responses and a corresponding decrease of 308 annual hours.

In compiling these estimates, we consulted our records of the number of infant formula submissions received in the past. All infant formula submissions may be provided to us in electronic format. The hours per response reporting estimates are based on our experience with similar programs and information received from industry.

The total estimated annual reporting burden is 2,188 hours, as shown in table 1.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

FD&C act or 21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Burden per record	Total hours
Part 106—SUBPART B: CGMP Requirements	5	429.8	2,149	4.4	9,414
Part 106—SUBPARTS C–G: Quality control; audits; quality factors; records and reports	5	726.8	3,634	6	21,818
Part 107—SUBPART C; Exempt infant formulas	3	10	30	300	9,000
Exempt infant formula production; GMP; audits, recordkeeping, & reports	3	634	1,902	45	85,590
Total					125,822

[1] There are no capital costs or operating and maintenance costs associated with the information.
[2] Numbers have been rounded.

The total estimated annual recordkeeping burden is 125,822 hours, as shown in table 2.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Nutrient labeling; §§ 107.10(a) and 107.20	5	13	65	8	520

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

We estimate compliance with our infant formula labeling requirements in §§ 107.10(a) and 107.20 requires 520 hours annually.

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26537 Filed 12–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information: HIV National Strategic Plan 2021–2025 Available for Public Comment

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services' (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health (OASH) announces the draft HIV National Strategic Plan: A Roadmap to End the HIV Epidemic (2021–2025) (HIV Plan) available for public comment. The draft HIV Plan may be reviewed at *www.hiv.gov.*

DATES: All comments must be received by 5:00 p.m. ET on December 14, 2020 to be considered.

ADDRESSES: All comments must be submitted electronically to *HIVPlanComments@hhs.gov* to be considered.

FOR FURTHER INFORMATION CONTACT: Harold J. Phillips, OIDP, *Harold.Phillips@hhs.gov,* 202–725–8872.

SUPPLEMENTARY INFORMATION: The National HIV/AIDS Strategy, first released in 2010 and updated in 2015, changed the way that Americans talk about HIV and the ways that stakeholders prioritize and coordinate resources and deliver prevention and care services that support people with HIV or at risk for HIV. As a result, the nation's new HIV infections have declined from their peak in the mid-1980s—although remaining stable over the past decade—and people with HIV in care and treatment are living longer, healthier lives. In 2018 the estimated number of new HIV infections was 36,400. A robust prevention toolbox that includes pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), and syringe services programs (SSPs) has lowered a person's risk of acquiring HIV. Research in recent years has proven that people with HIV who take antiretroviral therapy achieve and maintain an undetectable viral load, not protect their health but also have effectively no risk of transmitting HIV through sex.

This stability in the annual number of new infections, though, has further illuminated opportunities for focused efforts. According to the most recent available data, less than one-half (38.9%) of the U.S. population have ever been tested for HIV [1] and an estimated 161,800 (14%) people with HIV are unaware of their status.[2] Only 63% of people diagnosed with HIV are virally suppressed.[3] Approximately 80% of new HIV infections are due to people who do not know they have HIV or are not receiving regular care,[4] and only 18% of the approximately 1.2 million people indicated for PrEP are receiving it.[5 6]

To respond and address the HIV public health epidemic, OASH through OIDP, in collaboration with a steering committee composed of a wide array of federal partners, has led and coordinated development of the HIV Plan. Opportunities for public input were provided, and public comments received were reviewed and analyzed, to help inform development of the components of the HIV Plan. The HIV Plan covers the entire country, provides a roadmap across the federal government, non-federal partners and stakeholders in all sectors of society, and encourages integration of several key components that are vital to our collective work.

The HIV Plan is the nation's third consecutive national HIV strategy. It sets forth bold targets for ending the HIV epidemic in the United States by 2030, including a 75% reduction in new HIV infections by 2025 and a 90% reduction by 2030. The HIV Plan articulates goals, objectives, and strategies to prevent new infections, treat people with HIV to improve health outcomes, reduce HIV-related disparities, and better integrate and coordinate the efforts of all partners to end the HIV epidemic in the United States. The HIV Plan also establishes indicators to measure progress, with quantitative targets for each indicator, and designates populations disproportionately impacted by and at risk for HIV as well as key areas of focus.

The order of goals, objectives, and strategies does not indicate any prioritization, and many are intertwined. The following are the HIV Plan's vision and four goals:

Vision: The United States will be a place where new HIV infections are prevented, every person knows their status, and every person with HIV has high-quality care and treatment and lives free from stigma and discrimination. This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race,

[1] National HIV Testing Day—June 27, 2019. MMWR. 2019;68:561. doi: *http://dx.doi.org/10.15585/mmwr.mm6825a1.*

[2] Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2014–2018. *HIV Surveillance Supplemental Report* 2020;25(1). Accessed September 28, 2020. *http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.*

[3] Harris NS, Johnson AS, Huang YLA, et al. *Vital Signs:* status of human immunodeficiency virus testing, viral suppression, and HIV preexposure prophylaxis—United States, 2013–2018. *MMWR.* 2019;68:1117–1123. doi: *http://dx.doi.org/10.15585/mmwr.mm6848e1.*

[4] Li Z, Purcell DW, Sansom SL, et al. *Vital Signs:* HIV transmission along the continuum of care—United States, 2016. *MMWR.* 2019;68:267–272. Figure 1. doi: *http://dx.doi.org/10.15585/mmwr.mm6811e1.*

[5] Harris NS, Johnson AS, Huang YLA, et al. *Vital Signs:* status of human immunodeficiency virus testing, viral suppression, and HIV preexposure prophylaxis—United States, 2013–2018. *MMWR.* 2019;68:1117–1123. doi: *http://dx.doi.org/10.15585/mmwr.mm6848e1.*

[6] Centers for Disease Control and Prevention. HIV Surveillance Data Tables (early release): Core indicators for monitoring the Ending the HIV Epidemic initiative (preliminary data): HIV diagnoses and linkage to HIV medical care, 2019 (reported through December 2019); and preexposure prophylaxis (PrEP)—2018, updated. *HIV Surveillance Data Tables* 2020;1(2). Accessed October 16, 2020. *https://www.cdc.gov/hiv/library/reports/surveillance-data-tables/index.html.*

ethnicity, religion, disability, geographic location, or socioeconomic circumstance.

Goals

1. Prevent new HIV infections;
2. Increase knoweldge of HIV status;
3. Reduce HIV-related disparities and health inequities; and
4. Achieve integrated, coordinated efforts that adddress the HIV epidemic among all partners and stakeholders.

Information Needs

The draft HIV Plan may be reviewed at: *www.hiv.gov.*

OIDP seeks to obtain feedback from external stakeholders on the following:

1. Do the draft plan's goals, objectives, and strategies appropriately address the HIV epidemic?
2. Are there any critical gaps in the HIV Plan's goals, objectives, and strategies? If so, please specify the gaps.
3. Do any of the HIV Plan's goals, objectives and strategies cause concern? If so, please specify the goal, objective or strategy, and describe the concern regarding it.

Each commenter is limited to a maximum of seven pages.

Authority: 77 FR 15761 (March 16, 2012).

Dated: November 25, 2020.

B. Kaye Hayes,

Acting Director, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2020–26586 Filed 12–1–20; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group Neuroscience Review Subcommittee.

Date: March 3, 2021.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700 B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2116, MSC 6902, Bethesda, MD 20892, 301–443–0800, *bbuzas@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: November 25, 2020.

Patricia B. Hansberger,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–26561 Filed 12–1–20; 8:45 am]

BILLING CODE 4140–01–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–631 and 731–TA–1463–1464 (Final)]

Forged Steel Fittings From India and Korea

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of forged steel fittings from India and Korea, provided for in subheadings 7307.92.30, 7307.92.90, 7307.93.30, 7307.93.60, 7307.93.90, 7307.99.10, 7307.99.30, and 7307.99.50 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV''), and to be subsidized by the government of India.[2]

Background

The Commission instituted these investigations effective October 23, 2019, following receipt of petitions filed with the Commission and Commerce by Bonney Forge Corporation (''Bonney''), Mount Union, Pennsylvania, and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (''USW''), Pittsburgh, Pennsylvania. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of forged steel fittings from India were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on June 19, 2020 (85 FR 37109). In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission conducted its hearing through written testimony and video conference on October 15, 2020. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on November 25, 2020. The views of the Commission are contained in USITC Publication 5137 (November 2020), entitled *Forged Steel Fittings from India and Korea: Investigation Nos. 701–TA–631 and 731–TA–1463–1464 (Final).*

By order of the Commission.

Issued: November 25, 2020.

Jessica Mullan,

Attorney Advisor.

[FR Doc. 2020–26579 Filed 12–1–20; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Vice Chair Randolph J. Stayin not participating.

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0084]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension With Change of a Currently Approved Collection Application and Permit for Temporary Importation of Firearms and Ammunition by Nonimmigrant Aliens—ATF Form 6NIA (5330.3D)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until February 1, 2021.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: Desiree M. Dickinson, EPS/IMPORTS/FESD, either by mail at 244 Needy Road, Martinsburg, WV 25405, by email at *desiree.dickinson@atf.gov,* or by telephone at 304–616–4550.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

— Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

— Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

— Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

— Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83):* Extension with change of a currently approved collection.

2. *The Title of the Form/Collection:* Application and Permit for Temporary Importation of Firearms and Ammunition By Nonimmigrant Aliens.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 6NIA (5330.3D).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households.

Other (if applicable): None.

Abstract: The Application and Permit for Temporary Importation of Firearms and Ammunition By Nonimmigrant Aliens—ATF Form 6NIA (5330.3D) is used by nonimmigrant aliens to temporarily import firearms and ammunition into the United States for hunting or other sporting purposes.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 15,000 respondents will utilize the form annually, and it will take each respondent approximately 30 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 7,500 hours, which is equal to 15,000 (# of respondents) * .5 (30 minutes).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: November 27, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–26585 Filed 12–1–20; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Modification to Consent Decree Under The Comprehensive Environmental Response, Compensation, and Liability Act

On November 25, 2020, the Department of Justice lodged a proposed consent decree modification (''Modification'') with the United States District Court for the Eastern District of Michigan in the lawsuit entitled *United States* v. *BASF Corp.,* et al., Civil Action No. 92–40071.

The original consent decree required the defendants in the case to perform cleanup work at the Rasmussen Dump Superfund Site in Brighton, Michigan. The defendants have performed most of the necessary work and are continuing to perform operation and maintenance. The proposed Modification adjusts the financial assurance provisions of the consent decree. As originally approved by the Court, defendants were required to maintain $10 million in financial assurance. Because most of the necessary work has been done, the Parties have agreed to reduce the financial assurance amount to $700,000 and change the financial assurance language to track that used in similar current consent decrees. The Modification makes no other changes to the consent decree.

The publication of this notice opens a period for public comment on the Modification. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *BASF Corp.,* D.J. Ref. No. 90–11–3–281/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the Modification may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Modification upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree

Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $5 (25 cents per page reproduction cost) payable to the United States Treasury.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–26545 Filed 12–1–20; 8:45 am]

BILLING CODE 4410–15–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Form PF, [SEC File No. 270–636, OMB Control No. 3235–0679]

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''Paperwork Reduction Act''), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 204(b)–1 (17 CFR 275.204(b)–1) under the Investment Advisers Act of 1940 (15 U.S.C. 80b–1 *et seq.*) implements sections 404 and 406 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act'') by requiring private fund advisers that have at least $150 million in private fund assets under management to report certain information regarding the private funds they advise on Form PF. These advisers are the respondents to the collection of information.

Form PF is designed to facilitate the Financial Stability Oversight Council's (''FSOC'') monitoring of systemic risk in the private fund industry and to assist FSOC in determining whether and how to deploy its regulatory tools with respect to nonbank financial companies. The Commission and the Commodity Futures Trading Commission may also use information collected on Form PF in their regulatory programs, including examinations, investigations and investor protection efforts relating to private fund advisers.

Form PF divides respondents into two broad groups, Large Private Fund Advisers and smaller private fund advisers. ''Large Private Fund Advisers'' are advisers with at least $1.5 billion in assets under management attributable to hedge funds (''large hedge fund advisers''), advisers that manage ''liquidity funds'' and have at least $1 billion in combined assets under management attributable to liquidity funds and registered money market funds (''large liquidity fund advisers''), and advisers with at least $2 billion in assets under management attributable to private equity funds (''large private equity advisers''). All other respondents are considered smaller private fund advisers.

The Commission estimates that most filers of Form PF have already made their first filing, and so the burden hours applicable to those filers will reflect only ongoing burdens, and not start-up burdens. Accordingly, the Commission estimates the total annual reporting and recordkeeping burden of the collection of information for each respondent is as follows:

(a) For smaller private fund advisers making their first Form PF filing, an estimated amortized average annual burden of 23 hours for each of the first three years;

(b) for smaller private fund advisers that already make Form PF filings, an estimated amortized average annual burden of 15 hours for each of the next three years;

(c) for large hedge fund advisers making their first Form PF filing, an estimated amortized average annual burden of 658 hours for each of the first three years;

(d) for large hedge fund advisers that already make Form PF filings, an estimated amortized average annual burden of 600 hours for each of the next three years;

(e) for large liquidity fund advisers making their first Form PF filing, an estimated amortized average annual burden of 588 hours for each of the first three years;

(f) for large liquidity fund advisers that already make Form PF filings, an estimated amortized average annual burden of 280 hours for each of the next three years;

(g) for large private equity advisers making their first Form PF filing, an estimated amortized average annual burden of 133 hours for each of the first three years; and

(h) for large private equity advisers that already make Form PF filings, an estimated amortized average annual burden of 100 hours for each of the next three years.

With respect to annual internal costs, the Commission estimates the collection of information will result in 127.06 burden hours per year on average for each respondent. With respect to external cost burdens, the Commission estimates a range from $0 to $50,000 per adviser.

Estimates of average burden hours and costs are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms. Compliance with the collection of information requirements of Form PF is mandatory for advisers that satisfy the criteria described in Instruction 1 to the Form. Responses to the collection of information will be kept confidential to the extent permitted by law. The Commission does not intend to make public information reported on Form PF that is identifiable to any particular adviser or private fund, although the Commission may use Form PF information in an enforcement action. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, C/O Cynthia Roscoe, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 27, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26591 Filed 12–1–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE Washington, DC 20549–2736

Extension:
Rule 17f–2 (d), [SEC File No. 270–036, OMB Control No. 3235–0028]

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17f–2(d) (17 CFR 240.17f–2(d)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17f–2(d) requires that records created pursuant to the fingerprinting requirements of Section 17(f)(2) of the Act be maintained and preserved by every member of a national securities exchange, broker, dealer, registered transfer agent and registered clearing agency (''covered entities'' or ''respondents''); permits, under certain circumstances, the records required to be maintained and preserved by a member of a national securities exchange, broker, or dealer to be maintained and preserved by a self–regulatory organization that is also the designated examining authority for that member, broker or dealer; and permits the required records to be preserved on microfilm. The general purpose for Rule 17f–2 is to: (i) Identify security risk personnel; (ii) provide criminal record information so that employers can make fully informed employment decisions; and (iii) deter persons with criminal records from seeking employment or association with covered entities. The rule enables the Commission or other examining authority to ascertain whether all required persons are being fingerprinted and whether proper procedures regarding fingerprinting are being followed. Retention of these records for a period of not less than three years after termination of a covered person's employment or relationship with a covered entity ensures that law enforcement officials will have easy access to fingerprint cards on a timely basis. This in turn acts as an effective deterrent to employee misconduct.

Approximately 3,900 respondents are subject to the recordkeeping requirements of the rule. Each respondent maintains approximately 68 new records per year, each of which takes approximately 2 minutes per record to maintain, for an annual burden of approximately 2.2666667 hours (68 records times 2 minutes). The total annual time burden for all respondents is approximately 8,840 hours (3,900 respondents times 2.2666667 hours). As noted above, all records maintained subject to the rule must be retained for a period of not less than three years after termination of a covered person's employment or relationship with a covered entity. In addition, we estimate the total annual cost burden to respondents is approximately $39,000 in third party storage costs.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 27, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26588 Filed 12–1–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 17f–2(c), [SEC File No. 270–035, OMB Control No. 3235–0029]

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17f–2(c) (17 CFR 240.17f–2(c)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17f–2(c) allows persons required to be fingerprinted pursuant to Section 17(f)(2) of the Act to submit their fingerprints to the Attorney General of the United States or its designee (*i.e.,* the Federal Bureau of Investigation (''FBI'')) through a registered national securities exchange or a registered national securities association (collectively, also known as ''self–regulatory organizations'' or ''SROs'') pursuant to a fingerprint plan filed with, and declared effective by, the Commission. Fingerprint plans have been declared effective for the American, Boston, Chicago, New York, and Philadelphia stock exchanges and for the Financial Industry Regulatory Authority (''FINRA'') and the Chicago Board Options Exchange. Currently, FINRA accounts for the bulk of the fingerprint submissions.

It is estimated that 3,900 respondents submit approximately 281,804 sets of fingerprints (consisting of approximately 253,721 electronic sets and 28,083 hard copy sets) to SROs on an annual basis. The Commission estimates that it would take approximately 15 minutes to create and submit each fingerprint card. The total time burden is therefore estimated to be approximately 70,451 hours, or approximately 18 hours per respondent, annually.

In addition, the SROs charge an estimated $26 fee for processing fingerprint cards submitted electronically, resulting in a total annual cost to all 3,900 respondents of approximately $6,596,746 or approximately $1,691 per respondent per year. The SROs charge an estimated $41 fee for processing fingerprint cards submitted in hard copy, resulting in a total annual cost to all 3,900 respondents of approximately $1,151,403, or approximately $295 per respondent per year. The combined

annual cost to all respondents is thus approximately $7,748,149.

Because the FBI will not accept fingerprint cards directly from submitting organizations, Commission approval of fingerprint plans from certain SROs is essential to carry out the Congressional goal to fingerprint securities industry personnel. Filing these plans for review assures users and their personnel that fingerprint cards will be handled responsibly and with due care for confidentiality.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 27, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26589 Filed 12–1–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34123]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

November 27, 2020.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of November 2020. A copy of each application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at http://www.sec.gov/search/search.htm or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below. Hearing requests should be received by the SEC by 5:30 p.m. on December 22, 2020, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary at *Secretarys-Office@sec.gov*.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov*.

FOR FURTHER INFORMATION CONTACT: Shawn Davis, Assistant Director, at (202) 551–6413 or Chief Counsel's Office at (202) 551–6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE, Washington, DC 20549–8010.

AIP Macro Registered Fund P [File No. 811–22683]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On May 17, 2019, August 28, 2019, December 20, 2019, April 2, 2020, and July1, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $44,500 incurred in connection with the liquidation were paid by the applicant. Applicant also has retained approximately $26,000 for the purpose of paying outstanding liabilities.

Filing Date: The application was filed on August 14, 2020.

Applicant's Address: Jonathan.gaines@dechert.com.

Asia Pacific Fund, Inc. [File No. 811–04710]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On January 31, 2019, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $296,572 incurred in connection with the liquidation were paid by the applicant. Applicant also has retained approximately $10,792 for the purpose of paying final accrued liabilities.

Filing Dates: The application was filed on December 20, 2019 and amended on November 13, 2020.

Applicant's Address: JKopcsik@stradley.com.

Bread & Butter Fund Inc. [File No. 811–21748]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On July 31, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $1,852 incurred in connection with the liquidation were paid by the applicant's investment adviser.

Filing Dates: The application was filed on August 28, 2020, and amended on October 23, 2020.

Applicant's Address: jpotkul@potkulcapital.com.

CC Real Estate Income Master Fund [File No. 811–23134]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On August 3, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $27,816 incurred in connection with the liquidation were paid by the applicant. Applicant also has retained $125,386 for the purpose of paying outstanding obligations.

Filing Date: The application was filed on August 18, 2020.

Applicant's Address: Clifford.cone@cliffordchance.com.

Eagle Growth and Income Opportunities Fund [File No. 811–22839]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On August 3, 2020; August 24, 2020; and November 20, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $1,791,596 incurred in connection with the liquidation were paid by the applicant. Applicant also has retained $1,658,038 for the purpose of paying outstanding obligations. Applicant has agreed to the following condition to deregistration under the Act:

None of the fund's current or prior investment advisers or any of their respective ''affiliated persons'' (as defined in the Investment Company Act of 1940, as amended) will receive any fee or other payment, directly or indirectly, from the remaining assets; provided, however, that pro rata distributions by the fund to its shareholders shall be permissible.

Filing Date: The application was filed on November 23, 2020.

Applicant's Address: NRunyan@proskauer.com.

Goldman Sachs MLP Income Opportunities Fund [File No. 811–22856]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Goldman Sachs MLP and Energy Renaissance Fund, and on September 28, 2020 made a final distribution to its shareholders based on net asset value. Expenses of $365,820.16 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on October 30, 2020.

Applicant's Address: william.bielefeld@dechert.com.

Nuveen Texas Quality Municipal Income Fund [File No. 811–06384]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Nuveen Quality Municipal Income Fund, and on March 2, 2020 made a final distribution to its shareholders based on net asset value. Expenses of $476,085 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on October 9, 2020.

Applicant's Address: dglatz@stradley.com.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26590 Filed 12–1–20; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2020–0030]

Privacy Act of 1974; System of Records

AGENCY: Office of Research, Demonstration, and Employment Support, Office of Retirement and Disability Policy, Social Security Administration (SSA).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act, we are issuing public notice of our intent to modify an existing system of records entitled, Disability Analysis File (DAF) and the National Beneficiary Survey (NBS) Data System (60–0382), last published on December 21, 2018. This notice publishes details of the modified system as set forth below under the caption, **SUPPLEMENTARY INFORMATION**.

DATES: The system of records notice (SORN) is applicable upon its publication in today's **Federal Register**, with the exception of the new routine uses, which are effective January 4, 2021. We invite public comment on the routine uses or other aspects of this SORN. In accordance with 5 U.S.C. 552a(e)(4) and (e)(11), we are providing the public a 30-day period in which to submit comments. Therefore, please submit any comments by January 4, 2021.

ADDRESSES: The public, Office of Management and Budget (OMB), and Congress may comment on this publication by writing to the Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, or through the Federal e-Rulemaking Portal at *http://www.regulations.gov*. Please reference docket number SSA–2020–0030. All comments we receive will be available for public inspection at the above address and we will post them to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Talya White, Government Information Specialist, Privacy Implementation Division, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, telephone: (410) 966–5855, email: *talya.white@ssa.gov* and Tristin Dorsey, Government Information Specialist, Privacy Implementation Division, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, telephone: (410) 966–5855, email: *tristin.dorsey@ssa.gov*.

SUPPLEMENTARY INFORMATION: We are modifying the language in routine use No. 3 to clarify the type of access authorized to organizations and agencies for research and statistical activities.

In addition, we are adding a new routine use to permit disclosures to the Census Bureau, for the purpose of providing SSA-approved organizations and agencies access to DAF–NBS records at Census Bureau Federal Statistical Research Data Centers for authorized research and statistics activities. We are also updating the records retention and disposal schedule.

Lastly, we are modifying the notice throughout to correct miscellaneous stylistic formatting and typographical errors of the previously published notice, and to ensure the language reads consistently across multiple systems. We are republishing the entire notice for ease of reference.

In accordance with 5 U.S.C. 552a(r), we have provided a report to OMB and Congress on this modified system of records.

Matthew Ramsey,

Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.

SYSTEM NAME AND NUMBER:

Disability Analysis File (DAF) and the National Beneficiary Survey (NBS) Data System, 60–0382.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Social Security Administration, Office of Retirement and Disability Policy, Office of Research, Demonstration, and Employment Support, 6401 Security Boulevard, Baltimore, Maryland 21235.

SYSTEM MANAGER(S):

Social Security Administration, Deputy Commissioner for Retirement and Disability Policy, Office of Research, Demonstration, and Employment Support, 6401 Security Boulevard, Baltimore, Maryland 21235, (410) 966–5855.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 234, 1106, and 1110 of the Social Security Act, as amended, and SSA Regulations (20 CFR 401.165).

PURPOSE(S) OF THE SYSTEM:

We will use the information in this system to perform research about SSDI and/or SSI beneficiaries. We may also grant outside researchers access to information in this system when conducting SSA-approved research. Researchers and statisticians use the data to perform in-depth research including, but not limited to, examining the medical, economic, and social consequences of limitations in work

activity for individuals with disabilities and their families; program planning and evaluation; evaluation of proposals for policy and legislative changes; and to determine the characteristics of program applicants and benefit recipients.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains information about past, present, and potential beneficiaries (*e.g.,* denied applicants) of SSDI and SSI, as well as, State Vocational Rehabilitation programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of records that include name; Social Security number (SSN); socioeconomic data (*e.g.,* education, work, and earnings); demographics (*e.g.,* date of birth, date of death, sex, and state of residence); medical characteristics (*e.g.,* number of limitations, self-reported health, mental health score); disability characteristics (*e.g.*, primary diagnosis code and dual eligibility); information concerning subjects (*e.g.,* health, self-reported health status, work experience, and family relationships); benefits (*e.g.,* combined SSI and SSDI); and use of medical and rehabilitative services (*e.g.,* agency closure type and service use).

RECORD SOURCE CATEGORIES:

We obtain information in this system of records from existing SSA systems of records, including but not limited to 60–0050, Completed Determination Record—Continuing Disability Determinations; 60–0058, Master File of Social Security Number (SSN) Holders and SSN Applications; 60–0090, Master Beneficiary Record; 60–0103, Supplemental Security Income Record and Special Veterans Benefits; 60–0221, Vocational Rehabilitation Reimbursement Case Processing System; 60–0295, Ticket-to-Work and Self-Sufficiency Program Payment Database; and 60–0320, Electronic Disability (eDIB) Claim File.

The system also contains data from system of records 60–0059, Earnings Recording and Self-Employment Income System. Only SSA staff have access to data from the Earnings Recording and Self-Employment Income System.

We also obtain information in this system of records from other Federal agencies (*e.g.,* the U.S. Census Bureau and U.S. Department of Education (*e.g.,* the Rehabilitation Services Administration, for vocational rehabilitation program applicant or participant data)); surveys (*e.g.,* the National Beneficiary Survey); and other extramural research conducted under agreements, contracts, and grants between SSA and other agencies or entities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

We will disclose records pursuant to the following routine uses; however, we will not disclose any information defined as ''return or return information'' under 26 U.S.C. 6103 of the Internal Revenue Code (IRC), unless authorized by a statute, the Internal Revenue Service (IRS), or IRS regulations.

1. To contractors and other Federal agencies, as necessary, for the purpose of assisting SSA in the efficient administration of its programs. We will disclose information under this routine use only in situations in which we may enter into a contractual or similar agreement with a third party to assist in accomplishing an agency function relating to this system of records.

2. To contractors, cooperative agreement awardees, State agencies, Federal agencies, and Federal congressional support agencies for research and statistical activities that are designed to increase knowledge about present or alternative Social Security programs; are of importance to the Social Security program or beneficiaries; or are for an epidemiological project that relates to the Social Security program or beneficiaries. We will disclose information under this routine use pursuant only to a written agreement with SSA.

3. To organizations and agencies that have been granted access to DAF–NBS records onsite at SSA or offsite at Census Bureau Federal Statistical Research Data Centers for research and statistics activities that are designed to increase knowledge about present or alternative Social Security programs; are of importance to the Social Security program or the Social Security beneficiaries; or are for an epidemiological project that relates to the Social Security program or beneficiaries. We will disclose information under this routine use pursuant only to a written agreement between the organization or agency and SSA.

4. To student volunteers, individuals working under a personal services contract, and other workers who technically do not have the status of Federal employees, when they are performing work for SSA, as authorized by law, and they need access to personally identifiable information (PII) in SSA records in order to perform their assigned agency functions.

5. To a congressional office in response to an inquiry from that office made on behalf of, and at the request of, the subject of the record or third party acting on the subject's behalf.

6. To the Office of the President, in response to an inquiry from that office made on behalf of, and at the request of, the subject of record or a third party acting on the subject's behalf.

7. To the Department of Justice (DOJ), a court or other tribunal, or another party before such court or tribunal, when:

(a) SSA, or any component thereof; or

(b) any SSA employee in his or her official capacity; or

(c) any SSA employee in his or her individual capacity where DOJ (or SSA where it is authorized to do so) has agreed to represent the employee; or

(d) the United States or any agency thereof where we determine the litigation is likely to affect SSA or any of its components, is a party to the litigation or has an interest in such litigation, and we determine that the use of such records by DOJ, a court or other tribunal, or another party before the tribunal is relevant and necessary to the litigation, provided, however, that in each case, we determine that such disclosure is compatible with the purpose for which the records were collected.

8. To Federal, State and local law enforcement agencies and private security contractors, as appropriate, information necessary:

(a) To enable them to protect the safety of SSA employees and customers, the security of the SSA workplace, and the operation of our facilities; or

(b) to assist in investigations or prosecutions with respect to activities that affect such safety and security or activities that disrupt the operation of our facilities.

9. To the National Archives and Records Administration (NARA) under 44 U.S.C. 2904 and 2906.

10. To appropriate agencies, entities, and persons when:

(a) SSA suspects or has confirmed that there has been a breach of the system of records;

(b) SSA has determined that as a result of the suspected or confirmed breach, there is a risk of harm to individuals, SSA (including its information systems, programs, and operations), the Federal Government, or national security; and

(c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connections with SSA's efforts to respond to the suspected or confirmed

breach or to prevent, minimize, or remedy such harm.

11. To another Federal agency or Federal entity, when we determine that information from this system of records is reasonably necessary to assist the recipient agency or entity in:

(a) Responding to a suspected or confirmed breach; or

(b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

12. To the Census Bureau, for the purpose of providing SSA-approved organizations and agencies access to DAF–NBS records at Census Bureau Federal Statistical Research Data Centers for authorized research and statistics activities.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

We will maintain records in this system in paper form (*e.g.,* questionnaire forms, computer printouts) and in electronic form (*e.g.,* magnetic tape and disc).

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

We will retrieve records in this system by case number or SSN. We will also retrieve records by socioeconomic, demographic, medical, and disability characteristics.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

In accordance with NARA rules codified at 36 CFR 1225.16, we maintain records in accordance with agency-specific records schedule NC1–47–78–21, item I.A.3.a.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

We retain electronic and paper files with personal identifiers in secure storage areas accessible only by our authorized employees and contractors who have a need for the information when performing their official duties. Security measures include the use of codes and profiles, personal identification number and password, and personal identification verification cards. We keep paper records in locked cabinets within secure areas, with access limited to only those employees who have an official need for access in order to perform their duties. To the maximum extent consistent with the approved research needs, we purge personal identifiers from micro-data files prepared for purposes of research and subject these files to procedural safeguards to assure anonymity.

We annually provide our employees and contractors with appropriate security awareness training that includes reminders about the need to protect PII and the criminal penalties that apply to unauthorized access to, or disclosure of, PII (5 U.S.C. 552a(i)(1)). Furthermore, employees and contractors with access to databases maintaining PII must sign a sanctions document annually, acknowledging their accountability for inappropriately accessing or disclosing such information.

In addition, all external researchers accessing the DAF–NBS system of records will be required to complete the appropriate security awareness training, which includes reminders about the need to protect PII and the criminal penalties that apply to unauthorized access to, or disclosure of, PII.

RECORD ACCESS PROCEDURES:

Individuals may submit requests for notification of, or access to, information about them contained in this system by submitting a written request to the system manager at the above address, which includes their name, SSN, or other information that may be in this system of records that will identify them. Individuals requesting notification of, or access to, a record by mail must include (1) a notarized statement to verify their identity or (2) must certify in the request that they are the individual they claim to be and that they understand that the knowing and willful request for, or acquisition of, a record pertaining to another individual under false pretenses is a criminal offense.

Individuals requesting notification of, or access to, records may also make an in-person request by providing their name, SSN, or other information that may be in this system of records that will identify them, as well as provide an identifying document, preferably with a photograph, such as a driver's license. Individuals lacking identification documents sufficient to establish their identity must certify in writing that they are the individual they claim to be and that they understand that the knowing and willful request for, acquisition of, a record pertaining to another individual under false pretenses is a criminal offense. These procedures are in accordance with our regulations at 20 CFR 401.40 and 401.45.

CONTESTING RECORD PROCEDURES:

Same as record access procedures. Individuals should also reasonably identify the record, specify the information they are contesting, and state the corrective action sought and the reasons for the correction with supporting justification showing how the record is incomplete, untimely, inaccurate, or irrelevant. These procedures are in accordance with our regulations at 20 CFR 401.65(a).

NOTIFICATION PROCEDURES:

Same as record access procedures. These procedures are in accordance with our regulations at 20 CFR 401.40 and 401.45.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

83 FR 65779, Disability Analysis File (DAF) and National Beneficiary Survey (NBS) Data System.

[FR Doc. 2020–26535 Filed 12–1–20; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Delegation of Authority No.492]

Delegation of the Authority To Submit to the Congress Certain Notifications and Explanations Relating to the Voluntary Offer Agreement

By virtue of the authority vested in the Secretary of State, including Section 1 of the State Department Basic Authorities Act, as amended (22 U.S.C. 2651a) and the Presidential Memorandum dated September 2, 2020, relating to Section 1 of the July 2, 1980, Senate Resolution of Advice and Consent to Ratification of the Agreement between the United States of America and the International Atomic Energy Agency for the Application of Safeguards in the United States of America, with attached Protocol, signed at Vienna on November 18, 1977 (the ''Voluntary Offer Agreement''), I hereby delegate to the Assistant Secretary for International Security and Nonproliferation, to the extent authorized by law, the authority to provide to the Congress the notifications and explanations specified in Section 1 of the Senate's Resolution of Advice and Consent to Ratification of the Voluntary Offer Agreement.

Any act, executive order, regulation, or procedure subject to, or affected by, this delegation shall be deemed to be such act, executive order, regulation, or procedure as amended from time to time. The Secretary, the Deputy Secretary, and the Under Secretary for Arms Control and International Security may at any time exercise any authority

or function delegated by this delegation of authority.

This delegation of authority does not amend, supersede, or affect the validity of any other delegation of authority dealing with submission of reports to the Congress. This delegation of authority shall be published in the **Federal Register**.

Dated: November 3, 2020.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2020–26540 Filed 12–1–20; 8:45 am]

BILLING CODE 4710–27– P

DEPARTMENT OF STATE

[Public Notice 11271]

Request for Information for the 2021 Trafficking in Persons Report

ACTION: Request for information for the 2021 Trafficking in Persons Report.

SUMMARY: The Department of State (''the Department'') requests written information to assist in reporting on the degree to which the United States and foreign governments meet the minimum standards for the elimination of trafficking in persons (''minimum standards'') that are prescribed by the Trafficking Victims Protection Act of 2000, as amended (''TVPA''). This information will assist in the preparation of the Trafficking in Persons Report (''TIP Report'') that the Department submits annually to the U.S. Congress on governments' concrete actions to meet the minimum standards. Foreign governments that do not meet the minimum standards and are not making significant efforts to do so may be subject to restrictions on nonhumanitarian, nontrade-related foreign assistance from the United States, as defined by the TVPA. Submissions must be made in writing to the Office to Monitor and Combat Trafficking in Persons at the Department of State by February 1, 2021. Please refer to the *Addresses, Scope of Interest,* and *Information Sought* sections of this Notice for additional instructions on submission requirements.

DATES: Submissions must be received by 5 p.m. on February 1, 2021.

ADDRESSES: Written submissions and supporting documentation may be submitted by the following method:

- *Email: tipreport@state.gov* for submissions related to foreign governments and *tipreportUS@state.gov* for submissions related to the United States.

Scope of Interest: The Department requests information relevant to assessing the United States' and foreign governments' concrete actions to meet the minimum standards for the elimination of trafficking in persons during the reporting period (April 1, 2020–March 31, 2021). The minimum standards are listed in the *Background* section. Submissions must include information relevant to efforts to meet the minimum standards and should include, but need not be limited to, answering the questions in the *Information Sought* section. Submissions need not include answers to all the questions; only those questions for which the submitter has direct professional experience should be answered, and that experience should be noted. For any critique or deficiency described, please provide a recommendation to remedy it. Note the country or countries that are the focus of the submission.

Submissions may include written narratives that answer the questions presented in this Notice, research, studies, statistics, fieldwork, training materials, evaluations, assessments, and other relevant evidence of local, state/provincial, and federal/central government efforts. To the extent possible, precise dates and numbers of officials or citizens affected should be included.

Written narratives providing factual information should provide citations of sources, and copies of and links to the source material should be provided. Please send electronic copies of the entire submission, including source material. If primary sources are used, such as research studies, interviews, direct observations, or other sources of quantitative or qualitative data, provide details on the research or data-gathering methodology and any supporting documentation. The Department only includes in the TIP Report information related to trafficking in persons as defined by the TVPA; it does not include, and is therefore not seeking, information on prostitution, migrant smuggling, visa fraud, or child abuse, unless such crimes also involve the elements of sex trafficking or forced labor.

Confidentiality: Please provide the name, phone number, and email address of a single point of contact for any submission. It is Department practice not to identify in the TIP Report information concerning sources to safeguard those sources. Please note, however, that any information submitted to the Department may be releasable pursuant to the provisions of the Freedom of Information Act or other applicable law. Submissions related to the United States will be shared with U.S. government agencies, as will submissions relevant to efforts by other U.S. government agencies.

Response: This is a request for information only; there will be no response to submissions.

SUPPLEMENTARY INFORMATION:

1. Background

Definitions: The TVPA defines ''severe forms of trafficking in persons'' as:

- Sex trafficking: The recruitment, harboring, transportation, provision, obtaining, patronizing, or soliciting of a person for the purpose of a commercial sex act that is induced by force, fraud, or coercion, or in which the person induced to perform such act has not attained 18 years of age.
- Forced labor (also known as labor trafficking): The recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion, for the purposes of involuntary servitude, peonage, debt bondage, or slavery.
- Child soldiering: Child soldiering is a form of human trafficking when a government armed group, (including police or other security force), paramilitary organization, rebel group, or other non-state armed group unlawfully recruits or uses children—through force, fraud, or coercion—as combatants or in other support roles, including as cooks, porters, guards, messengers, medics, guards, servants, spies, or sex slaves.

The TIP Report: The TIP Report is the most comprehensive worldwide report on governments' efforts to combat trafficking in persons. It represents an annually updated, global look at the nature and scope of trafficking in persons and the broad range of government actions to confront and eliminate it. The U.S. government uses the TIP Report to inform diplomacy, to encourage partnership in creating and implementing laws and policies to combat trafficking, and to target resources on prevention, protection, and prosecution programs. Worldwide, international organizations, foreign governments, and nongovernmental organizations use the TIP Report as a tool to examine where resources are most needed. Prosecuting traffickers, protecting victims, and preventing trafficking are the ultimate goals of the TIP Report and of the U.S government's anti-trafficking policy.

The Department prepares the TIP Report with information from across the U.S. government, foreign government officials, nongovernmental and international organizations, survivors of trafficking in persons, published

reports, and research trips to every region. The TIP Report focuses on concrete actions that governments take to fight trafficking in persons, including prosecutions, convictions, and sentences for traffickers, as well as victim identification and protection measures and prevention efforts. Each TIP Report narrative also includes prioritized recommendations for each country. These recommendations are used to assist the Department in measuring governments' progress from one year to the next and determining whether governments meet the minimum standards for the elimination of trafficking in persons or are making significant efforts to do so.

The TVPA creates a four-tier ranking system. Tier placement is based principally on the extent of concrete government action to combat trafficking. The Department first evaluates whether the government fully meets the TVPA's minimum standards for the elimination of trafficking. Governments that do so are placed on Tier 1. For other governments, the Department considers the extent of such efforts. Governments that are making significant efforts to meet the minimum standards are placed on Tier 2. Governments that do not fully meet the minimum standards and are not making significant efforts to do so are placed on Tier 3. Finally, the Department considers Special Watch List criteria and, when applicable, places countries on Tier 2 Watch List. For more information, the 2020 TIP Report can be found at *www.state.gov/reports/2020-trafficking-in-persons-report/*.

Since the inception of the TIP Report in 2001, the number of countries included and ranked has more than doubled; the 2020 TIP Report included 188 countries and territories. Around the world, the TIP Report and the promising practices reflected therein have inspired legislation, national action plans, policy implementation, program funding, protection mechanisms that complement prosecution efforts, and a stronger global understanding of this crime.

Since 2003, the primary reporting on the United States' anti-trafficking activities has been through the annual Attorney General's Report to Congress and Assessment of U.S. Government Activities to Combat Human Trafficking (''AG Report'') mandated by section 105 of the TVPA (22 U.S.C. 7103(d)(7)). Since 2010, the TIP Report, through a collaborative interagency process, has included an assessment of U.S. government anti-trafficking efforts in light of the minimum standards to eliminate trafficking in persons set forth by the TVPA.

II. Minimum Standards for the Elimination of Trafficking in Persons

The TVPA sets forth the minimum standards for the elimination of trafficking in persons as follows:

(1) The government of the country should prohibit severe forms of trafficking in persons and punish acts of such trafficking.

(2) For the knowing commission of any act of sex trafficking involving force, fraud, coercion, or in which the victim of sex trafficking is a child incapable of giving meaningful consent, or of trafficking which includes rape or kidnapping or which causes a death, the government of the country should prescribe punishment commensurate with that for grave crimes, such as forcible sexual assault.

(3) For the knowing commission of any act of a severe form of trafficking in persons, the government of the country should prescribe punishment that is sufficiently stringent to deter and that adequately reflects the heinous nature of the offense.

(4) The government of the country should make serious and sustained efforts to eliminate severe forms of trafficking in persons.

The following factors should be considered as indicia of serious and sustained efforts to eliminate severe forms of trafficking in persons:

(1) Whether the government of the country vigorously investigates and prosecutes acts of severe forms of trafficking in persons, and convicts and sentences persons responsible for such acts, that take place wholly or partly within the territory of the country, including, as appropriate, requiring incarceration of individuals convicted of such acts. For purposes of the preceding sentence, suspended or significantly reduced sentences for convictions of principal actors in cases of severe forms of trafficking in persons shall be considered, on a case-by-case basis, whether to be considered as an indicator of serious and sustained efforts to eliminate severe forms of trafficking in persons. After reasonable requests from the Department of State for data regarding investigations, prosecutions, convictions, and sentences, a government which does not provide such data, consistent with the capacity of such government to obtain such data, shall be presumed not to have vigorously investigated, prosecuted, convicted, or sentenced such acts. During the periods prior to the annual report submitted on June 1, 2004, and on June 1, 2005, and the periods afterwards until September 30 of each such year, the Secretary of State may disregard the presumption contained in the preceding sentence if the government has provided some data to the Department of State regarding such acts and the Secretary has determined that the government is making a good faith effort to collect such data.

(2) Whether the government of the country protects victims of severe forms of trafficking in persons and encourages their assistance in the investigation and prosecution of such trafficking, including provisions for legal alternatives to their removal to countries in which they would face retribution or hardship, and ensures that victims are not inappropriately incarcerated, fined, or otherwise penalized solely for unlawful acts as a direct result of being trafficked, including by providing training to law enforcement and immigration officials regarding the identification and treatment of trafficking victims using approaches that focus on the needs of the victims.

(3) Whether the government of the country has adopted measures to prevent severe forms of trafficking in persons, such as measures to inform and educate the public, including potential victims, about the causes and consequences of severe forms of trafficking in persons, measures to establish the identity of local populations, including birth registration, citizenship, and nationality, measures to ensure that its nationals who are deployed abroad as part of a diplomatic, peacekeeping, or other similar mission do not engage in or facilitate severe forms of trafficking in persons or exploit victims of such trafficking, a transparent system for remediating or punishing such public officials as a deterrent, measures to prevent the use of forced labor or child labor in violation of international standards, effective bilateral, multilateral, or regional information sharing and cooperation arrangements with other countries, and effective policies or laws regulating foreign labor recruiters and holding them civilly and criminally liable for fraudulent recruiting.

(4) Whether the government of the country cooperates with other governments in the investigation and prosecution of severe forms of trafficking in persons and has entered into bilateral, multilateral, or regional law enforcement cooperation and coordination arrangements with other countries.

(5) Whether the government of the country extradites persons charged with

acts of severe forms of trafficking in persons on substantially the same terms and to substantially the same extent as persons charged with other serious crimes (or, to the extent such extradition would be inconsistent with the laws of such country or with international agreements to which the country is a party, whether the government is taking all appropriate measures to modify or replace such laws and treaties so as to permit such extradition).

(6) Whether the government of the country monitors immigration and emigration patterns for evidence of severe forms of trafficking in persons and whether law enforcement agencies of the country respond to any such evidence in a manner that is consistent with the vigorous investigation and prosecution of acts of such trafficking, as well as with the protection of human rights of victims and the internationally recognized human right to leave any country, including one's own, and to return to one's own country.

(7) Whether the government of the country vigorously investigates, prosecutes, convicts, and sentences public officials, including diplomats and soldiers, who participate in or facilitate severe forms of trafficking in persons, including nationals of the country who are deployed abroad as part of a diplomatic, peacekeeping, or other similar mission who engage in or facilitate severe forms of trafficking in persons or exploit victims of such trafficking, and takes all appropriate measures against officials who condone such trafficking. A government's failure to appropriately address public allegations against such public officials, especially once such officials have returned to their home countries, shall be considered inaction under these criteria. After reasonable requests from the Department of State for data regarding such investigations, prosecutions, convictions, and sentences, a government which does not provide such data consistent with its resources shall be presumed not to have vigorously investigated, prosecuted, convicted, or sentenced such acts. During the periods prior to the annual report submitted on June 1, 2004, and June 1, 2005, and the periods afterwards until September 30 of each such year, the Secretary of State may disregard the presumption contained in the preceding sentence if the government has provided some data to the Department of State regarding such acts and the Secretary has determined that the government is making a good faith effort to collect such data.

(8) Whether the percentage of victims of severe forms of trafficking in the country that are non-citizens of such countries is insignificant.

(9) Whether the government has entered into effective, transparent partnerships, cooperative arrangements, or agreements that have resulted in concrete and measurable outcomes with

(A) domestic civil society organizations, private sector entities, or international nongovernmental organizations, or into multilateral or regional arrangements or agreements, to assist the government's efforts to prevent trafficking, protect victims, and punish traffickers; or

(B) the United States toward agreed goals and objectives in the collective fight against trafficking.

(10) Whether the government of the country, consistent with the capacity of such government, systematically monitors its efforts to satisfy the criteria described in paragraphs (1) through (8) and makes available publicly a periodic assessment of such efforts.

(11) Whether the government of the country achieves appreciable progress in eliminating severe forms of trafficking when compared to the assessment in the previous year.

(12) Whether the government of the country has made serious and sustained efforts to reduce the demand for

(A) commercial sex acts; and

(B) participation in international sex tourism by nationals of the country.

III. Information Sought Relevant to the Minimum Standards

Submissions should include, but need not be limited to, answers to relevant questions below for which the submitter has direct professional experience. Citations to source material should also be provided. Note the country or countries that are the focus of the submission. Please see the *Scope of Interest* section above for detailed information regarding submission requirements.

Trafficking Profile

1. Describe the country's trafficking situation, including the forms of trafficking that occur, industries and sectors in which traffickers exploit victims, countries/regions in which traffickers recruit victims, locations and regions in which trafficking occurs, and recruitment methods. What groups are at particular risk of human trafficking? Are citizens of the country identified as victims of human trafficking abroad? Does child sex tourism occur in the country or involve its nationals abroad, and if so, in which countries? Have trafficking methods and trends changed in the past 12 months, including as a result of the COVID–19 pandemic?

2. What was the extent of official complicity in trafficking crimes? Were officials—including police, immigration officials, diplomats, peacekeepers, military personnel—government contractors, or government grantees directly or indirectly facilitating or enabling trafficking in persons? Did they operate as traffickers, enable traffickers, or take actions that may facilitate trafficking (including accepting bribes to allow undocumented border crossings or suspending active investigations of suspected traffickers, etc.)?

3. Was there a government policy or pattern of human trafficking, such as in government-funded or -affiliated services or programs within the country or abroad? Did government policies, regulations, or agreements relating to migration, labor, trade, and investment facilitate vulnerabilities to, or incidence of, forced labor or sex trafficking? Were there examples of trafficking occurring in state institutions (*e.g.,* prisons, orphanages or child foster homes, institutions for mentally or physically disabled persons, camps, compounds, or outposts)? If so, what measures did the government take to end such practices?

4. What proactive measures did the government take to prevent official complicity in trafficking in persons crimes? How did the government respond to reports of complicity that arose during the reporting period, including investigations, prosecutions, convictions, and sentencing of complicit officials? Were these efforts sufficient?

5. Is there evidence that nationals of the country deployed abroad as part of a diplomatic, peacekeeping, or other similar mission have engaged in or facilitated trafficking, including in domestic servitude? Has the government vigorously investigated, prosecuted, convicted, and sentenced nationals engaged in these activities?

Overview

6. What were the government's major accomplishments in addressing human trafficking since April 1, 2020? In what significant ways have the government's efforts to combat trafficking in persons changed in the past year? How have new laws, regulations, policies, or implementation strategies (*e.g.,* substantive criminal laws and procedures, mechanisms for civil remedies, and victim-witness security, generally and in relation to court proceedings) affected its anti-trafficking response?

7. Over the past year, what were the greatest deficiencies in the government's anti-trafficking efforts? What were the limitations on the government's ability

to address human trafficking problems in practice?

8. If the government had a national action plan to address trafficking, how was it implemented in practice? Were NGOs and other relevant civil society stakeholders consulted in the development and implementation of the plan? Did the government fund, partially fund, or not fund the plan?

9. How has the COVID–19 pandemic affected the government's efforts to coordinate, execute, and monitor its anti-trafficking response, if at all? How have anti-trafficking officials, units, and coordinating bodies continued to operate and adapt?

10. Have investigative agencies and courts adapted to impacts from COVID–19? If so, how? Do police, prosecutors, and courts continue to process trafficking cases and/or has the volume of these cases changed? What has been the impact on officials' ability to collect evidence, including victim testimony?

11. Please provide additional information and/or recommendations to improve the government's anti-trafficking efforts overall.

12. Please highlight effective strategies and practices that other governments could consider adopting.

Prosecution

13. Please provide observations regarding the implementation of existing laws, policies and procedures. Are there gaps in anti-trafficking legislation that could be amended to improve the government's response? Are there any government policies that have undermined or otherwise negatively affected anti-trafficking efforts within that country?

14. Do government officials understand the nature of all forms of trafficking? If not, please provide examples of misconceptions or misunderstandings. Did the government effectively provide or support anti-trafficking trainings for officials? If not, how could they be improved?

15. Please provide observations on overall anti-trafficking law enforcement efforts and the efforts of police and prosecutors to pursue trafficking cases. Were any trafficking cases investigated and/or prosecuted, and were any traffickers convicted during the reporting period—including under trafficking-specific laws and non-trafficking laws? Is the government equally vigorous in pursuing forced labor and sex trafficking, internal and transnational trafficking, and crimes that involve its own nationals or foreign citizens? If not, why?

16. Please note any efforts to investigate and prosecute suspects for knowingly soliciting or patronizing a sex trafficking victim to perform a commercial sex act. Does law enforcement pursue trafficking cases that would hold accountable corporations for forced labor in supply chains within the country?

17. Do judges appear appropriately knowledgeable and sensitized to trafficking cases? Do they implement and encourage trauma-informed practices in their courts?

18. What sentences have courts imposed upon traffickers? Are these sentences generally strict enough to reflect the serious nature of the crime, and are they comparable to sentences for other similar crimes, such as rape and kidnapping? How common are fines, suspended sentences, and prison time of less than one year for convicted traffickers?

Protection

19. Did the government make a coordinated, proactive effort to identify victims of all forms of trafficking? If the government had any written procedures for screening for trafficking, were those procedures sufficient and implemented effectively by officials? What steps do officials take if a potential case of human trafficking is identified? Are those steps sufficient? Did officials effectively coordinate among one another and with relevant nongovernmental organizations to conduct screenings and refer victims to care? Is there any trafficking screening conducted before deportation or when detaining migrants, including unaccompanied minors? Are interpreters available for screening foreign victims? If commercial sex is legalized or decriminalized, how did health officials, labor inspectors, or police identify trafficking victims among persons involved in commercial sex? If commercial sex is illegal, did the government proactively identify trafficking victims during raids or other encounters with commercial sex establishments? How has the COVID–19 pandemic affected the government's victim identification and referral efforts, if at all?

20. Does the government operate a hotline for potential victims? If so, what are the hours of operation? What languages could it accommodate? Were victims identified and cases referred to law enforcement as a result of calls to the hotline? What did the government do to publicize the hotline? Did it remain in operation during the COVID–19 pandemic?

21. What victim services are available and provided (legal, medical, food, shelter, interpretation, mental health care, employment, training, etc.)? Who provides these services? If nongovernment organizations provide the services, does the government support their work either financially or otherwise? Are these service providers required to be trained on human trafficking and victim identification? How has the COVID–19 pandemic affected government and NGO efforts to provide shelter, medical, and psycho-social care to victims?

22. What was the overall quality of victim care? How could victim services be improved? Was government funding for trafficking victim protection and assistance adequate? Are there gaps in access to victim services? Are services available regardless of geographic location within the country? Are services victim-centered and trauma-informed?

23. Are services provided adequately to victims of both labor and sex trafficking? Adults and children, including men and boys? Citizens and noncitizens of all ethnic backgrounds or nationalities? LGBTI persons? Persons with disabilities? Were such benefits linked to whether a victim assisted law enforcement or participated in a trial, or whether a trafficker was convicted? Could victims choose independently whether to enter a shelter, and could they leave at will if residing in a shelter? Could adult victims leave shelter premises unchaperoned? Could victims seek employment and work while receiving assistance?

24. Do service providers and law enforcement work together cooperatively, for instance to share information about trafficking trends or to plan for services after a raid? What is the level of cooperation, communication, and trust between service providers and law enforcement?

25. Were there means by which victims could obtain restitution from defendants in criminal cases or file civil suits against traffickers for damages, and did this happen in practice? Did prosecutors request and/or courts order restitution in all cases where it was required, and if not, why?

26. How did the government encourage victims to assist in the investigation and prosecution of trafficking? How did the government protect victims during the trial process? If a victim was a witness in a court case, was the victim permitted to obtain employment, move freely about the country, or leave the country pending trial proceedings? How did the government work to ensure victims were not re-traumatized during participation in trial proceedings? Could victims provide testimony via video or

written statements? Were victims' identities kept confidential as part of such proceedings? In what ways could the government support increased participation of victims in prosecutions against their traffickers?

27. Did the government provide, through a formal policy or otherwise, temporary or permanent residency status, or other relief from deportation, for foreign victims of human trafficking who may face retribution or hardship in the countries to which they would be deported? Were foreign victims given the opportunity to seek legal employment while in this temporary or permanent residency? Were such benefits linked to whether a victim assisted law enforcement, participated in a trial or whether there was a successful prosecution? Does the government repatriate victims who wish to return home or assist with third country resettlement? Are victims awaiting repatriation or third country resettlement offered services? Are victims indeed repatriated, or are they deported? Did the government extend additional immigration relief to victims who would otherwise be deported or repatriated to countries with a high risk of COVID–19 infection or who could not return to their home countries due to travel restrictions?

28. Does the government effectively assist its nationals exploited abroad? Does the government work to ensure victims receive adequate assistance and support for their repatriation while in destination countries? Does the government provide adequate assistance to repatriated victims after their return to their countries of origin, and if so, what forms of assistance?

29. Does the government arrest, detain, imprison, or otherwise punish trafficking victims (whether or not identified as such by authorities) for unlawful acts their traffickers compelled them to commit (forgery of documents, illegal immigration, unauthorized employment, prostitution, theft, or drug production or transport, etc.)? If so, do these victims disproportionately represent a certain gender, race, ethnicity, or other group or particular type of trafficking? Does law enforcement screen for trafficking victims when detaining or arresting individuals engaged in commercial sex or individuals that may be at particular risk of human trafficking?

Prevention

30. What efforts has the government made to prevent human trafficking? Please describe any government-funded anti-trafficking information or education campaigns or training, whether aimed at the public or at specific sectors or stakeholders/actors. Did these campaigns or trainings target potential trafficking victims, potential first responders or other trusted authorities, known trafficking sectors or vulnerabilities, and/or the demand for human trafficking (*e.g.,* buyers of commercial sex or goods produced with forced labor)? Does the government provide financial support to nongovernment organizations working to promote public awareness?

31. How did the government regulate, oversee, and screen for trafficking indicators in the labor recruitment process, including for both licensed and unlicensed recruitment and placement agencies, individual recruiters, sub-brokerages, and microfinance lending operations? Did it maintain labor attachés abroad and were they trained on human trafficking indicators? How effective were these efforts in preventing abuse?

32. What did the government do to regulate recruitment practices that are known to contribute to trafficking in persons? Specifically, did the government prohibit (in any context) charging workers recruitment fees? Also indicate if the government prohibited the recruitment of workers through knowingly fraudulent job offers (including misrepresenting wages, working conditions, location, or nature of the job), contract switching, and confiscating or otherwise denying workers access to their identity documents. If there are laws or regulations on recruitment, did the government effectively enforce them?

33. What steps did the government take to minimize the trafficking risks faced by migrant workers departing from or arriving in the country and to raise awareness among potential labor migrants about the risks of human trafficking, legal limits on recruitment fees, or their rights while abroad? Did the government coordinate with other governments (*e.g.,* via bilateral agreements with migrant labor sending or receiving countries) on safe and responsible recruitment that included prevention measures to target known trafficking indicators? To what extent were these implemented? Are workers (both nationals of the country and foreign nationals) in all industries (*e.g.,* domestic work, agriculture, etc.) equally and sufficiently protected under existing labor laws?

34. What did the government do to ensure that its policies, regulations, and agreements relating to migration, labor, trade, and investment did not facilitate trafficking?

35. How did the government's response to the COVID–19 pandemic affect the ability of migrant workers to continue earning an income, to enter and exit the country, and to maintain their immigration status? What steps did the government take to mitigate the increased risk of human trafficking some migrant workers may have faced due to the pandemic (job creation or placement for out-of-work labor migrants, extension of immigration relief, etc.)?

36. If the government has entered into bilateral, multilateral, or regional anti-trafficking information-sharing and cooperation arrangements, are they effective and have they resulted in concrete and measurable outcomes? If not, why?

37. Did the government provide assistance to other governments in combating trafficking in persons through trainings or other assistance programs?

38. What measures has the government taken to reduce the participation by nationals of the country in international and domestic child sex tourism?

39. Did the government take sufficient measures to establish the identity of local populations, including birth registration and issuance of documentation, citizenship, and nationality?

Child Soldiering

40. Did government officials engage in, support, or otherwise facilitate the unlawful recruitment or use of children in the government's armed forces, police, or other security forces? [NOTE: This can include combat roles as well as support roles, but please be specific in this regard if possible.] Did the government provide support to any armed groups that recruited and/or used child soldiers in combat or support roles? What was the extent of the support (*e.g.,* in-kind, financial, training, etc.)? Describe the conditions of military detention of child soldiers and/or children accused of association with armed groups, including: (1) The typical length of time the children are held; (2) access to legal aid and rehabilitation services; (3) the conditions of the detention facility including food, sanitation, crowding, etc. and whether children are segregated from adults and by gender; (4) allegations of suspected sexual exploitation while in detention, including of female child soldiers; and (5) allegations children and/or child soldiers are used for labor, intelligence gathering, or to screen other detained persons.

41. Please provide observations regarding government efforts to address the issue of unlawful recruitment or use of children by governmental armed groups and/or non-state armed groups. Describe the government's efforts to disarm and demobilize child soldiers, to provide protection services and reintegrate former child soldiers, and to monitor the wellbeing of such children after reintegration. Does the government have any children held in military detention due to their suspected roles as child soldiers? Do international monitoring organizations (*e.g.,* UN, ICRC, HRW) have unhindered access to interview these detained children and/or child soldiers and monitor the conditions of their detention? Describe the conditions of military detention of child soldiers and/or children accused of association with armed groups. Does the government have and/or use any hand-over procedures to transfer these children to civilian authorities?

Catherine E. Kay,

Deputy Director, Office to Monitor and Combat Trafficking in Persons, Department of State.

[FR Doc. 2020–26576 Filed 12–1–20; 8:45 am]

BILLING CODE 4710–17–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36458]

West Virginia State Rail Authority—Acquisition and Operation Exemption—The Elk River Railroad, Inc.

West Virginia State Rail Authority (WVRA), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire from The Elk River Railroad, Inc. (TERRI) and operate approximately 18.0 miles of rail line extending from milepost 0.0 at Dundon and milepost 18.0 at Widen, in Clay County, W. Va. (the Line).[1]

WVRA states that it has executed a Purchase and Sale Agreement with TERRI to purchase the Line, plus connecting spur and side tracks, if any, appurtenant property and assets, and underlying real estate and right-of-way. WVRA states that, after consummation, it will own and operate the Line as a common carrier and will assume all common carrier rights and obligations with respect thereto.

WVRA certifies that the proposed acquisition and operation of the Line does not involve a provision or agreement that may limit future interchange with a third-party connecting carrier. WVRA further certifies that its projected annual revenues as a result of this transaction will not exceed the maximum revenue of a Class III rail carrier and will not exceed $5 million.

The transaction may be consummated on or after December 16, 2020, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 9, 2020 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36458, should be filed with the Surface Transportation Board via e-filing on the Board's website. In addition, a copy of each pleading must be served on WVRA's representative, Lucinda K. Butler, Executive Director, West Virginia State Rail Authority, 120 Water Plant Drive, Moorefield, WV 26836.

According to WVRA, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: November 25, 2020.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2020–26574 Filed 12–1–20; 8:45 am]

BILLING CODE 4915–01–P

[1] The verified notice states that the Line is known as the Buffalo Creek & Gauley Railroad. TERRI was recently granted after-the-fact authority to merge with The Buffalo Creek Railroad Company, which previously owned the Line. *See Elk River R.R.—Merger Exemption—Buffalo Creek R.R.,* FD 36434 (STB served Nov. 6, 2020).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Publication of the Tier 2 Tax Rates

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: Publication of the tier 2 tax rates for calendar year 2021 as required by section 3241(d) of the Internal Revenue Code. Tier 2 taxes on railroad employees, employers, and employee representatives are one source of funding for benefits under the Railroad Retirement Act.

DATES: The tier 2 tax rates for calendar year 2021 apply to compensation paid in calendar year 2021.

FOR FURTHER INFORMATION CONTACT: Kathleen Edmondson, CC:EEE:EOET:ET1, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, Telephone Number (202) 317–6798 (not a toll-free number).

SUPPLEMENTARY INFORMATION: TIER 2 TAX RATES: The tier 2 tax rate for 2021 under section 3201(b) on employees is 4.9 percent of compensation. The tier 2 tax rate for 2021 under section 3221(b) on employers is 13.1 percent of compensation. The tier 2 tax rate for 2021 under section 3211(b) on employee representatives is 13.1 percent of compensation.

Dated: November 20, 2020.

Rachel D. Levy,

Associate Chief Counsel (Employee Benefits, Exempt Organizations and Employment Taxes).

[FR Doc. 2020–26559 Filed 12–1–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Transfer of Property Seized/Forfeited by a Treasury Forfeiture Fund Participating Agency

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to comment on the proposed information collections listed below, in accordance with the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before February 1, 2021.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8100, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Spencer W. Clark by emailing *PRA@treasury.gov,* calling (202) 927–5331, or viewing the entire

information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Title: Request for Transfer of Property Seized/Forfeited by a Treasury Forfeiture Fund Participating Agency.

OMB Control Number: 1505–0152.

Type of Review: Revision of a currently approved request.

Description: This form is an application from local law enforcement entities to the Treasury Department to request a percentage of proceeds or tangible property that has been seized/forfeited by the federal government.

Form: TD F 92–22.46.

Affected Public: Federal, state and local law enforcement agencies participating in the Department of the Treasury Asset Sharing Program.

Estimated Number of Respondents: 7,000.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 7,000.

Estimated Time per Response: 30 Minutes.

Estimated Total Annual Burden Hours: 3,500.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: November 27, 2020.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2020–26583 Filed 12–1–20; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0823]

Agency Information Collection Activity Under OMB Review: Expanded Access to Non-VA Care Through the MISSION Act: Veterans Community Care Program

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Health Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden, and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0823.''

FOR FURTHER INFORMATION CONTACT: Danny S. Green, Office of Quality, Performance and Risk (OQPR), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 421–1354 or email *danny.green2@va.gov* Please refer to ''OMB Control No. 2900–0823'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Expanded Access to Non-VA Care through the MISSION Act: Veterans Community Care Program (VA Forms 10–10143, 10–10143a, 10–10143b, 10–10143c, 10–10143e, 10–10143f and 10–10143g).

OMB Control Number: 2900–0823.

Type of Review: Revision and extension of a currently approved collection.

Abstract: Section 101 of the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018 requires VA to implement the Veterans Community Care Program to furnish care in the community to covered Veterans through eligible entities and providers, under circumstances as further prescribed in the MISSION Act. VA currently collects information that will be required to implement the Veterans Community Care Program (VCCP) under the Veterans Choice Program, through an OMB approved collection 2900–0823.

OMB Collection 2900–0823 now includes VA Form 10–10143, Election to Receive Authorized Non-VA Care and Selection of Provider for the Veterans Community Care Program; VA Form 10–10143a, Veterans Community Care Health Insurance Certification; VA Form 10–10143b, Submission of Medical Record Information under the Veterans Community Care Program; VA Form 10–10143c, Submission of Information on Credentials and Licenses by Eligible Entities and Providers; and VA Form 10–10143e, Secondary Authorization Request for VA Community Care. In addition, two new forms that received emergency PRA clearances from OMB in 2020 are included in 2900–0823: VA Form 10–10143f, Community Care Document Cover Sheet; and VA Form 10–10143g, Non-VA Hospital Emergency Notification.

VA seeks to update OMB collection 2900–0823 to implement the Veterans Community Care Program by updating the title of VA forms and any associated statutory citations to be consistent with the new program and the MISSION Act, by adding a new cover sheet to use when submitting documentation from providers of non-VA emergent care, by adding a new 72-hour notification form to be used when a Veteran receives emergent care from a non-VA provider, and by updating burden hours to account for estimated increased use of community care under the new program.

This collection of information is required to properly adjudicate and implement the requirements of the MISSION Act.

a. VA Form 10–10143 will collect Veteran information on whether covered Veterans would elect to receive authorized care under the Veterans Community Care Program (VCCP) if certain conditions are met, as required by 38 U.S.C. 1703(d)(3). This form also will allow a covered Veteran to specify a particular non-VA entity or provider.

b. VA Form 10–10143a will collect other health insurance information from covered Veterans who elect to participate in the VCCP, as required by 38 U.S.C. 1705A. This information also is required by 38 U.S.C. 1703(j), which requires VA to recover or collect reasonable charges for community care that is furnished from a health care plan contract described in 38 U.S.C. 1729.

c. VA Form 10–10143b will collect health records of covered Veterans from non-VA health care entities and providers for care authorized under the VCCP, as required by 38 U.S.C. 1703(a)(2)(A), which requires VA to establish a mechanism to receive medical records from non-VA providers. A copy of all medical and dental records (including but not limited to images, test results, and notes or other records of what care was provided and why) related to a Veteran's care provided under the VCCP must be submitted to VA, including any claims for payment for the furnishing of such care.

d. VA Form 10–10143c will collect information from non-VA entities and providers concerning relevant credentials and licenses as required for such entities or providers to furnish care and services generally. This information is authorized by section 133 of the MISSION Act, which requires VA to establish competency standards for non-VA providers, as well as 38 U.S.C. 1703C(a)(1), which requires VA to establish certain standards of quality for furnishing care and services (including through non-VA providers).

e. VA Form 10–10143e will collect secondary authorization requests from non-VA entities and providers to furnish care and services in addition to or supporting the original authorization for care. This information is required by 38 U.S.C. 1703(a)(3), which establishes that a covered Veteran may only receive care or services under the VCCP upon VA's authorization of such care or services.

f. VA Form 10–10143f will allow for the submission of paper documents in support of a non-VA provider claim for emergency care rendered in the community when not accompanied by a paper Health Care Claim form. This Community Care Document Cover Sheet will be used exclusively for the submission of medical documentation for unauthorized emergent services for patients otherwise covered by VA.

g. VA Form 10–10143g will be used to provide 72-hour notification to VA when a Veteran receives emergent care from a non-VA provider. This form should be completed by the non-VA provider within 72 hours of the beginning of treatment.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 85 FR 158 on August 14, 2020, pages 49720 and 49721.

VA Form 10–10143

Affected Public: Individuals or households.

Estimated Annual Burden: 610,833 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 3,665,000.

VA Form 10–10143a

Affected Public: Individuals or households.

Estimated Annual Burden: 610,833 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 3,665,000.

VA Form 10–10143b

Affected Public: Private Sector.

Estimated Annual Burden: 1,039,332 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: Average of 34 times annually.

Estimated Number of Respondents: 366,823.

VA Form 10–10143c

Affected Public: Private Sector.

Estimated Annual Burden: 10,190 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 122,274.

VA Form 10–10143e

Affected Public: Private Sector.

Estimated Annual Burden: 611,372 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: Average of 5 times annually.

Estimated Number of Respondents: 366,823.

VA Form 10–10143f

Affected Public: Private Sector.

Estimated Annual Burden: 41,667 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 500,000.

VA Form 10–10143g

Affected Public: Private Sector.

Estimated Annual Burden: 83,333 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 500,000.

By direction of the Secretary.

Danny S. Green,

Interim VA Clearance Officer, Office of Quality, Performance and Risk (OQPR), Department of Veterans Affairs.

[FR Doc. 2020–26575 Filed 12–1–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0882]

Agency Information Collection Activity Under OMB Review: Chapter 31 Request for Assistance

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0882.

FOR FURTHER INFORMATION CONTACT: Danny S. Green, Enterprise Records Service (005R1B), Department of Veterans Affairs, 811 Vermont Avenue NW, Washington, DC 20420, (202) 421–1354 or email *danny.green2@va.gov.* Please refer to ''OMB Control No. 2900–0882'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 3100, 38 U.S.C. 501.

Title: Chapter 31 Request for Assistance (VA Form 28–10212).

OMB Control Number: 2900–0882.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 28–10212 is used to gather specific information regarding a claimant's request for services, supplies, or equipment that are necessary to participate in the Chapter 31 program.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on ≤this collection of information was published at insert citation date, 85 FR 182 on September, 18, 2020, pages 58428 and 58429.

Affected Public: Individuals.

Estimated Annual Burden: 83.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 500.

By direction of the Secretary.

Danny S. Green,

VA PRA Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2020–26566 Filed 12–1–20; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 85 Wednesday,

No. 232 December 2, 2020

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 411

Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS–1720–F]

RIN 0938–AT64

Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule addresses any undue regulatory impact and burden of the physician self-referral law. This final rule is being issued in conjunction with the Centers for Medicare & Medicaid Services' (CMS) Patients over Paperwork initiative and the Department of Health and Human Services' (the Department or HHS) Regulatory Sprint to Coordinated Care. This final rule establishes exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers. It also establishes a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; establishes a new exception for donations of cybersecurity technology and related services; and amends the existing exception for electronic health records (EHR) items and services. This final rule also provides critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations.

DATES: These regulations are effective on January 19, 2021, except for amendment number 3, which further amends section 411.352(i), which is effective January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Lisa O. Wilson, (410) 786–8852. Matthew Edgar, (410) 786–0698. Catherine Martin, (410) 786–8382.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory History

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payor) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. For additional information about section 1903(s) of the Act, *see* 66 FR 857 through 858.

This rulemaking follows a history of rulemakings related to the physician self-referral law. The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all designated health services) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was published in the **Federal Register** on January 4, 2001 as a final rule with comment period (66 FR 856). The second final rulemaking (Phase II) was published in the **Federal Register** on March 26, 2004 as an interim final rule with comment period (69 FR 16054). Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933). The third final rulemaking (Phase III) was published in the **Federal Register** on September 5, 2007 as a final rule (72 FR 51012).

In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the Fiscal Year (FY) 2009 Inpatient Prospective Payment System final rule with comment period (73 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including: (1) Revisions to the ''stand in the shoes'' provisions; (2) establishment of provisions regarding the period of disallowance and temporary noncompliance with signature requirements; (3) prohibitions on per unit of service (''per-click'') and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements; and (4) expansion of the definition of ''entity.''

After passage of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act), we issued final regulations on November 29, 2010 in the Calendar Year (CY) 2011 Physician Fee Schedule (PFS) final rule with comment period that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception (75 FR 73443). We also issued final regulations on November 24, 2010 in the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66987) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act. On November 16, 2015, in the CY 2016 PFS final rule, we issued regulations to reduce burden and facilitate compliance (80 FR 71300 through 71341). In that rulemaking, we established two new exceptions, clarified certain provisions of the physician self-referral regulations, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. On November 15, 2016, we included in the CY 2017 PFS final rule, at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B), requirements identical to regulations that have been in effect since October 1, 2009 that the rental charges for the lease of office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (81 FR 80533 through 80534).

On November 23, 2018, in our most recent substantive update, the CY 2019 PFS final rule (83 FR 59715 through 59717), we incorporated into our regulations provisions at sections 1877(h)(1)(D) and (E) of the Act that were added by section 50404 of the Bipartisan Budget Act of 2018 (Pub. L.

115–123). Specifically, we codified in regulations our longstanding policy that the writing requirement in various compensation arrangement exceptions in § 411.357 may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. We also amended the special rule for temporary noncompliance with signature requirements at § 411.353(g), removing the limitation on the use of the rule to once every 3 years with respect to the same physician and making other changes to conform the regulatory provision to section 1877(h)(1)(E) of the Act.

B. Health Care Delivery and Payment Reform: Transition to Value-Based Care

1. The Regulatory Sprint to Coordinated Care

The Department identified the broad reach of the physician self-referral law, as well as the Federal anti-kickback statute and beneficiary inducements civil monetary penalty (CMP) law, sections 1128B(b) and 1128A(a)(5) of the Act, respectively, as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and the coordination of care among providers in both the Federal and commercial sectors. Industry stakeholders informed us that, because the consequences of noncompliance with the physician self-referral law (and the anti-kickback statute) are so dire, providers, suppliers, and physicians may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs (or slow their rate of growth). To address these concerns, and to help accelerate the transformation of the health care system into one that better pays for value and promotes care coordination, HHS launched a Regulatory Sprint to Coordinated Care (the Regulatory Sprint), led by the Deputy Secretary of HHS. This Regulatory Sprint aims to remove potential regulatory barriers to care coordination and value-based care created by four key Federal health care laws and associated regulations: (1) The physician self-referral law; (2) the anti-kickback statute; (3) the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA); and (4) the rules under 42 CFR part 2 related to opioid and substance use disorder treatment. Through the Regulatory Sprint, HHS aims to encourage and improve—

- A patient's ability to understand treatment plans and make empowered decisions;
- Providers' alignment on an end-to-end treatment approach (that is, coordination among providers along the patient's full care journey);
- Incentives for providers to coordinate, collaborate, and provide patients with tools to be more involved; and
- Information-sharing among providers, facilities, and other stakeholders in a manner that facilitates efficient care while preserving and protecting patient access to data.

The Department believes that the realization of these goals would meaningfully improve the quality of care received by all American patients. As part of the Regulatory Sprint, CMS, the HHS Office of Inspector General (OIG), and the HHS Office for Civil Rights (OCR) each issued requests for information to solicit comments that may help to inform the Department's approach to achieving the goals of the Regulatory Sprint (83 FR 29524, 83 FR 43607, and 83 FR 64302, respectively). We discuss our request for information in this section of this final rule.

2. Policy Considerations and Other Information Relevant to the Development of This Final Rule

a. Medicare Payment Was Volume-Based When the Physician Self-Referral Statute Was Enacted

When the physician self-referral statute was enacted in 1989, under traditional fee-for-service (FFS) Medicare (that is, Parts A and B), the vast majority of covered services were paid based on volume. Although some services were ''bundled'' into a single payment, such as inpatient hospital services that were paid on the basis of the diagnosis-related group (DRG) that corresponded to the patient's diagnosis and the services provided (known as the Hospital Inpatient Prospective Payment System, or IPPS), in general, Medicare made a payment each time a provider or supplier furnished a service to a beneficiary. Thus, the more services a provider or supplier furnished, the more Medicare payments it would receive. Importantly, these bundled payments typically covered services furnished by a single provider or supplier, directly or by contract; payments were not bundled across multiple providers, with each billing independently. This volume-based reimbursement system continues to apply under traditional Medicare to both services paid under a prospective payment system (PPS) and services paid under a retrospective FFS system.

As described in this final rule, the physician self-referral statute was enacted to address concerns that arose in Medicare's volume-based reimbursement system where the more designated health services that a physician ordered, the more payments Medicare would make to the entity that furnished the designated health services. If the referring physician had an ownership or investment interest in the entity furnishing the designated health services, he or she could increase the entity's revenue by referring patients for more or higher value services, potentially increasing the profit distributions tied to the physician's ownership interest. Similarly, a physician who had a service or other compensation arrangement with an entity might increase his or her aggregate compensation if he or she made referrals that resulted in more Medicare payments to the entity. The physician self-referral statute was enacted to combat the potential that financial self-interest would affect a physician's medical decision making and ensure that patients have options for quality care. The law's prohibitions were intended to prevent a patient from being referred for services that are not needed or steered to less convenient, lower quality, or more expensive health care providers because the patient's physician may improve his or her financial standing through those referrals. This statutory structure was designed for and made sense in Medicare's then-largely volume-based reimbursement system.

b. The Medicare Shared Savings Program, the Center for Medicare and Medicaid Innovation, and Medicare's Transition to Value-Based Payment

Since the enactment of the physician self-referral statute in 1989, significant changes in the delivery of health care services and the payment for such services have occurred, both within the Medicare and Medicaid programs and for non-Federal payors and patients. For some time, CMS has engaged in efforts to align payment under the Medicare program with the quality of the care provided to our beneficiaries. Laws such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (MMA), the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA), and the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) guided our early efforts to move toward health care delivery and payment reform. More recently, the Affordable Care Act required significant changes to the Medicare program's

payment systems and provides the Secretary with broad authority to test innovative payment and service delivery models.

Section 3022 of the Affordable Care Act established the Medicare Shared Savings Program (Shared Savings Program). The Congress created the Shared Savings Program to promote accountability for a patient population and coordinate items and services under Medicare Parts A and B and encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery. In essence, the Shared Savings Program facilitates coordination among providers to improve the quality of care for Medicare FFS beneficiaries and reduce unnecessary costs. Physicians, hospitals, and other eligible providers and suppliers may participate in the Shared Savings Program by creating or participating in an accountable care organization (ACO) that agrees to be held accountable for the quality, cost, and experience of care of an assigned Medicare FFS beneficiary population. ACOs that successfully meet quality and savings requirements share a percentage of the achieved savings with Medicare. Since enactment, we have issued numerous regulations to implement and update the Shared Savings Program. For example, in keeping with the Secretary's vision for achieving value-based transformation by pioneering new payment models, in 2018, we finalized changes to the Shared Savings Program that are intended to put the program on a path toward achieving a more measurable move to value, demonstrate savings to the Medicare program, and promote a competitive and accountable marketplace (83 FR 67816). Specifically, we finalized a significant redesign of the participation options available under the Shared Savings Program to encourage ACOs to transition to two-sided risk models (in which they may share in savings and are accountable for repaying shared losses), increase savings and mitigate losses for the Medicare Trust Funds, and increase program integrity.[1]

Section 1115A of the Act, as added by section 3021 of the Affordable Care Act, established the Center for Medicare and Medicaid Innovation (the Innovation Center) within CMS. The purpose of the Innovation Center is to test innovative payment and service delivery models to reduce expenditures for the care furnished to patients in the Medicare and Medicaid programs and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of that care. Using its authority in section 1115A of the Act, the Innovation Center has tested numerous health care delivery and payment models in which providers, suppliers, and individual practitioners participate. Most Innovation Center models generally fall into three categories: Accountable care models, episode-based payment models, and primary care transformation models. The Innovation Center also tests initiatives targeted to the Medicaid and CHIP population and to Medicare-Medicaid (dual eligible) enrollees, and is focused on other initiatives to accelerate the development and testing of new payment and service delivery models, as well as to speed the adoption of best practices.[2]

The Congress also granted the Secretary broad authority to waive provisions of section 1877 of the Act and certain other Federal fraud and abuse laws when he determines it is necessary to implement the Shared Savings Program (*see* section 1899(f) of the Act) or test models under the Innovation Center's authority (*see* section 1115A(d)(1) of the Act).[3]

c. Commercial Payor and Provider-Driven Activity

Although payments made directly from a payor to a physician generally do not implicate the physician self-referral law unless the payor is itself an entity that furnishes designated health services, remuneration between physicians and other health care providers that provide care to a payor's enrolled patients (or subscribers) likely does implicate the physician self-referral law. Commercial payors and health care providers have implemented and continue to develop numerous innovative health care payment and care delivery models that do not include or specifically relate to CMS. Even though the physicians and health care providers that participate in these initiatives do not necessarily provide designated health services payable by Medicare as part of the initiatives, financial relationships between them may nonetheless implicate the physician self-referral law, which, in turn, may restrict referrals of Medicare patients.

d. Request for Information Regarding the Physician Self-Referral Law (CMS–1720–NC)

The Secretary identified four priorities for HHS, the first of which is transforming our health care system into one that pays for value. Dramatically different from the system that existed when the physician self-referral statute was enacted, a value-driven health care system pays for outcomes rather than procedures. We believe that a successful value-based system requires integration and coordination among physicians and other health care providers and suppliers. The Secretary laid out four areas of emphasis for building a system that delivers value: (1) Maximizing the promise of health information technology (IT); (2) improving transparency in price and quality; (3) pioneering bold new models in Medicare and Medicaid; and (4) removing government burdens that impede care coordination. (See *https://www.hhs.gov/about/leadership/secretary/priorities/index.html#value-based-healthcare*.) This final rule focuses primarily on the final two areas of emphasis for value-based transformation—pioneering new models in Medicare and Medicaid and removing regulatory barriers that impede care coordination.

As the Secretary and the Administrator of CMS (the Administrator) have acknowledged, there are burdens associated with the physician self-referral regulations that may be inhibiting health care professionals and organizations, especially with respect to care coordination. In 2017, through the annual payment rules, CMS requested comments on improvements that could be made to the health care delivery system to reduce unnecessary burdens for clinicians, other providers, and patients and their families. In response, commenters shared information regarding the barriers to participation in health care delivery and payment reform efforts, both public and private, as well as the burdens of compliance with the physician self-referral statute and regulations. As a result of our review of these comments, and with a goal of reducing regulatory burden and dismantling barriers to value-based care transformation while also protecting the integrity of the Medicare program, on June 25, 2018, we published in the **Federal Register** a Request for Information Regarding the Physician Self-Referral Law (the CMS RFI) seeking recommendations and input from the

[1] For more information about the Shared Savings Program, *see http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html.*

[2] For more information about the Innovation Center's innovative health care payment and service delivery models, *see https://innovation.cms.gov/.*

[3] For more information about waivers issued using these authorities and guidance documents related to specific waivers, *see https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.*

public on how to address any undue impact and burden of the physician self-referral statute and regulations (83 FR 29524).

Comments on the CMS RFI fell within five general themes. First, commenters requested new exceptions to the physician self-referral law to protect a variety of compensation arrangements between and among parties in CMS-sponsored alternative payment models and also those models that are sponsored by other payors, including Federal payors. Commenters also requested protection for care coordination arrangements, including arrangements where entities and physicians share resources to facilitate the care of their common patients. Generally, commenters recognized the need for appropriate safeguards in exceptions for arrangements among parties that participate in alternative payment models. Second, commenters requested a new exception to permit entities to donate cybersecurity technology and services to physicians. Third, commenters provided helpful feedback on terminology and concepts critical to the physician self-referral law, such as commercial reasonableness, fair market value, and compensation that ''takes into account'' the volume or value of referrals and is ''set in advance.'' Fourth, some commenters expressed concerns that new exceptions or easing current restrictions could exacerbate overutilization and other harms. For example, some commenters indicated that financial gain should never be permitted to influence medical decision making, and some expressed concern that value-based payment systems drive industry consolidation and reduce competition. Finally, a few commenters provided feedback on issues that were not specifically discussed in the CMS RFI, such as requests to eliminate or keep the statutory restrictions for physician-owned hospitals and requests to eliminate, expand, or limit the scope and availability of the in-office ancillary services exception. Commenters on the CMS RFI provided valuable information used to develop the proposals that we are finalizing in this final rule.

e. Notice of Proposed Rulemaking

In the October 17, 2019 **Federal Register**, we published a proposed rule (84 FR 55766) (the proposed rule) in which we proposed a comprehensive package of reforms to modernize and clarify the regulations that interpret the physician self-referral law. These proposed policies were developed in support of the CMS Patients over Paperwork initiative, the Regulatory Sprint, and based on our experience in administering the physician self-referral law, including the CMS Voluntary Self-Referral Disclosure Protocol (SRDP). The CMS Patients over Paperwork initiative emphasizes a commitment to removing regulatory obstacles to providers spending time with patients. Reducing unnecessary burden generally is a shared goal of the Patients over Paperwork initiative and the Regulatory Sprint. The Regulatory Sprint is focused specifically on identifying regulatory requirements or prohibitions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, encouraging and incentivizing coordinated care.

To facilitate the transition of our health care system to one that is based on value rather than volume, we proposed new exceptions to the physician self-referral law for value-based arrangements, along with integrally-related definitions for value-based enterprises, activities, arrangements, and purposes, the providers and suppliers that participate in a value-based enterprise, and the target patient population for whom the parties' efforts are undertaken. We also proposed new and revised policies that balance program integrity concerns against the burden of the physician self-referral law's referral and billing prohibitions by: Providing guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations; reassessing the scope of the statute's reach; and establishing new exceptions for common nonabusive compensation arrangements between physicians and the entities to which they refer Medicare beneficiaries for designated health services.

As part of the Regulatory Sprint and also in the October 17, 2019 **Federal Register**, OIG published a proposed rule under the anti-kickback statute and CMP law to address concerns regarding provisions in those statutes that may act as barriers to coordinated care (84 FR 55694). Because many of the compensation arrangements between parties that participate in alternative payment models and other novel financial arrangements implicate both the physician self-referral law and the anti-kickback statute, we coordinated closely with OIG in developing certain provisions of our proposals. Our aim was to promote alignment across our agencies, where appropriate, to ease the compliance burden on the regulated industry. In some cases, our proposals were different in application or potentially more restrictive than OIG's comparable proposals, in recognition of the differences in statutory structures, authorities, and penalties. In other cases, OIG's proposals were more restrictive. In the proposed rule, we stated that, for some arrangements, it may be appropriate for the anti-kickback statute, which is an intent-based criminal law, to serve as ''backstop'' protection for arrangements that might be protected by an exception to the strict liability physician self-referral law (84 FR 55772).

C. Application and Scope of the Physician Self-Referral Law

As we emphasized in the proposed rule, our intent in interpreting and implementing section 1877 of the Act has always been ''to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory language and intent,'' and we have not vacillated from this position (84 FR 55771; *see* also, 66 FR 860). Our 1998 proposed rule was informed by our review of the legislative history of section 1877 of the Act, consultation with our law enforcement partners about their experience implementing and enforcing the Federal fraud and abuse laws, and empirical studies of physicians' referral patterns and practices, which concluded that a physician's financial relationship with an entity can affect a physician's medical decision making and lead to overutilization. At the time of our earliest rulemakings, we did not have as much experience in administering the physician self-referral law or working with our law enforcement partners on investigations and actions involving violations of the physician self-referral law. Thus, despite our stated intention to interpret the law's prohibitions narrowly and the exceptions broadly, we proceeded with great caution when designing exceptions.

Over the past decade, we have vastly expanded our knowledge of the aspects of financial relationships that result in Medicare program or patient abuse. Our administration of the SRDP, which has received over 1,200 submissions since its inception in 2010, has provided us insight into thousands of financial relationships—most of which were compensation arrangements—that ran afoul of the physician self-referral law but posed little risk of Medicare program or patient abuse. We made revisions to our regulations and shared policy clarifications in the CY 2016 and

2019 PFS rulemakings to address many issues related to the documentation requirements in the statutory and regulatory exceptions to the physician self-referral law, but had not, until now, addressed other requirements in the regulatory exceptions that stakeholders identified as adding unnecessary complexity without increasing safeguards for program integrity. As described in more detail in section II of this final rule, we are eliminating certain requirements in our regulatory exceptions that may be unnecessary and revising existing exceptions. We are also establishing new exceptions for nonabusive arrangements for which there is currently no applicable exception to the physician self-referral law's referral and billing prohibitions.

D. Purpose of the Final Rule

This final rule modernizes and clarifies the regulations that interpret the Medicare physician self-referral law. Following an extensive review of policies that originated in the context of a health care delivery and payment system that operates based on the volume of services, and to support the innovation necessary for a health care delivery and payment system that pays for value, we are establishing new, permanent exceptions to the physician self-referral law for value-based arrangements and definitions for terminology integral to such a system. This final rule also includes clarifying provisions and guidance intended to reduce unnecessary regulatory burden on physicians and other health care providers and suppliers, while reinforcing the physician self-referral law's goal of protecting against program and patient abuse. Finally, we are establishing new exceptions for nonabusive arrangements for which there is currently no applicable exception to the physician self-referral law's referral and billing prohibitions.

II. Provisions of the Final Rule

A. Facilitating the Transition to Value-Based Care and Fostering Care Coordination

1. Background

Transforming our health care system into one that pays for value is one of the Secretary's priorities. As we stated in the proposed rule, there is broad consensus throughout the health care industry regarding the urgent need for a movement away from legacy systems that pay for care on a FFS basis (84 FR 55772). Identifying and addressing regulatory barriers to value-based care transformation is a critical step in this movement. We are aware of the effect the physician self-referral law may have on parties participating or considering participation in integrated care delivery models, alternative payment models, and arrangements to incent improvements in outcomes and reductions in cost, and we share the optimism of commenters on the CMS RFI and the proposed rule that the changes to the physician self-referral regulations will allow greater innovation and enable HHS to realize its goal of transforming the health care system into one that pays for value.

The health care landscape when the physician self-referral law was enacted bears little resemblance to the landscape of today. As many commenters on the CMS RFI and the proposed rule highlighted, the physician self-referral law was enacted at a time when the goals of the various components of the health care system were often in conflict, with each component competing for a bigger share of the health care dollar without regard to the inefficiencies that resulted for the system as a whole—in other words, a volume-based system. According to these commenters, the current physician self-referral regulations—intended to combat overutilization in a volume-based system—are outmoded because, by their nature, integrated care models protect against overutilization by aligning clinical and economic performance as the benchmarks for value. And, in general, the greater the economic risk that providers assume, the greater the economic disincentive to overutilize services. According to some of these commenters, the current prohibitions are even antithetical to the stated goals of policy makers, both in the Congress and within HHS, for health care delivery and payment reform. We agree in concept and, as described below in this section II.A. of this final rule, we are finalizing an interwoven set of definitions and exceptions that depart from the historic exceptions to the physician self-referral law in order to facilitate the transition to a value-based health care delivery and payment system.

We intend for the policies finalized in this final rule to facilitate an evolving health care delivery system, and endeavored to design policies that will stand the test of time. We believe that our final policies achieve the right balance between ensuring program integrity, making compliance with the physician self-referral law readily achievable, and providing the flexibility required by participants in value-based health care delivery and payment systems. As we did with respect to the proposed rule, we coordinated closely with OIG in developing our final exceptions, definitions, and related policies. However, for the reasons described in this final rule, the final definitions and exceptions that pertain to the physician self-referral law differ in some respects from the final definitions and safe harbors that pertain to the anti-kickback statute. Compensation arrangements may implicate both statutes and, therefore, should be analyzed for compliance with each statute.

2. Definitions and Exceptions

In § 411.357(aa), we are finalizing new exceptions to the physician self-referral law for compensation arrangements that satisfy specified requirements based on the characteristics of the arrangement and the level of financial risk undertaken by the parties to the arrangement or the value-based enterprise of which they are participants. The exceptions apply regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both. Although revisions to the physician self-referral regulations are crucial to facilitating the transition to a value-based health care delivery and payment system, nothing in our final policies is intended to suggest that many value-based arrangements, such as pay-for-performance arrangements or certain risk-sharing arrangements, do not satisfy the requirements of existing exceptions to the physician self-referral law.

For purposes of applying the exceptions, we are finalizing new definitions at § 411.351 for the following terms: Value-based activity; value-based arrangement; value-based enterprise; value-based purpose; VBE participant; and target patient population. The definitions are essential to the application of the exceptions, which apply only to compensation arrangements that qualify as value-based arrangements. Thus, the exceptions may be accessed only by those parties that qualify as VBE participants in the same value-based enterprise. The definitions and exceptions together create the set of requirements for protection from the physician self-referral law's referral and billing prohibitions. Again, where possible and feasible, we have aligned with OIG's final policies to ease the compliance burden on the regulated industry. Specifically, with respect to the value-based terminology as defined in this final rule, we are aligned with the OIG in most respects, and points of difference are explained below.

To facilitate readers' review of our final policies, we first discuss the value-

based definitions we are finalizing in this final rule.

a. Definitions

The final definitions and exceptions together create the set of requirements for protection from the physician self-referral law's referral and billing prohibitions. The ''value-based'' definitions are interconnected and, for the best understanding, should be read together. In the proposed rule (84 FR 55773), we proposed the following terms and definitions for purposes of applying the new exceptions at § 411.357(aa):

- *Value-based activity* means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) The provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action. We also proposed that the making of a referral is not a value-based activity.
- *Value-based arrangement* means an arrangement for the provision of at least one value-based activity for a target patient population between or among: (1) The value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.
- *Value-based enterprise* means two or more VBE participants: (1) Collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).
- *Value-based purpose* means: (1) Coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.
- *VBE participant* means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.
- *Target patient population* means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s).

We are finalizing the definitions as proposed, with the modifications described below in this section II.A.2.a. of this final rule.

The activities undertaken by the parties to a compensation arrangement are key to the arrangement qualifying as a ''value-based arrangement'' to which the exceptions at § 411.357(aa) apply. We refer to these activities as value-based activities. In the proposed rule, we acknowledged that sometimes value-based activities are easily identifiable as the provision of items or services to a patient and, other times, identifying a specific activity responsible for an outcome in a value-based health care system can be difficult (84 FR 55773). We appreciate that remuneration paid in furtherance of the objectives of a value-based health care system does not always involve one-to-one payments for items or services provided by a party to an arrangement. For example, a shared savings payment distributed by an entity to a downstream physician who joined with other providers and suppliers to achieve the savings represents the physician's agreed upon share of such savings rather than a payment for specific items or services furnished by the physician to the entity (or on the entity's behalf). And, when payments are made to encourage a physician to adhere to a redesigned care protocol, such payments are made, in part, in consideration of the physician refraining from following or altering his or her past patient care practices rather than for direct patient care items or services provided by the physician. Therefore, at final § 411.351, ''value-based activity'' is defined to mean the provision of an item or service, the taking of an action, or the refraining from taking an action, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise of which the parties to the arrangement are participants. In the proposed rule, we stated that the act of referring patients for designated health services is itself not a value-based activity. In addition, as a general matter, referrals are not items or services for which a physician may be compensated under the physician self-referral law, and payments for referrals are antithetical to the purpose of the statute (84 FR 55773). Because of this view, we proposed to expressly state in the definition of ''value-based activity'' that the making of a referral is not a value-based activity in order to make clear that the exceptions would not protect the direct payment for referrals. For the reasons discussed in response to comments below, we are not finalizing this part of our proposal. However, as discussed in section II.D.2.c. of this final rule, we are revising the definition of ''referral'' at § 411.351 to affirm our policy that, as a general matter, referrals are not items or services for which a physician may be compensated under the physician self-referral law.

Our final definition of ''value-based activity'' requires that the activities must be reasonably designed to achieve at least one value-based purpose of the value-based enterprise. For example, if the value-based purpose of the enterprise is to coordinate and manage the care of patients who undergo lower extremity joint replacement procedures, a value-based arrangement might require routine post-discharge meetings between a hospital and the physician primarily responsible for the care of the patient following discharge from the hospital. The value-based activity—that is, the physician's participation in the post-discharge meetings—would be reasonably designed to achieve the enterprise's value-based purpose. In contrast, if the value-based purpose of the enterprise is to reduce the costs to or growth in expenditures of payors while improving or maintaining the quality of care for the target patient population, providing patient care services (the purported value-based activity) without monitoring their utilization would not appear to be reasonably designed to achieve that purpose.

The definition of ''value-based arrangement'' is key to our final policies aimed at facilitating the transition to value-based care and fostering care coordination, as the final exceptions apply only to arrangements that qualify as value-based arrangements. At final § 411.351, ''value-based arrangement'' is defined to mean an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (1) A value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise. We have revised the language of our proposed definition by substituting ''to which the only parties are'' for ''between or among'' to make clear that all parties to the value-based arrangement must be VBE participants in the same value-based enterprise. For

instance, a value-based arrangement between an imaging center and a physician would not be a value-based arrangement if the imaging center is not part of the same value-based enterprise as the physician. Effectively, the parties to a value-based arrangement must include an entity (as defined at § 411.351) and a physician; otherwise, the physician self-referral law's prohibitions would not be implicated. Also, because the exceptions at final § 411.357(aa) apply only to compensation arrangements (as defined at § 411.354(c)), the value-based arrangement must be a compensation arrangement and not another type of financial relationship to which the physician self-referral law applies.

Patient care coordination and management are the foundation of a value-based health care delivery system. Reform of the delivery of health care through better care coordination—including more efficient transitions for patients moving between and across care settings and providers,[4] reduction of orders for duplicative items and services, and open sharing of medical records and other important health data across care settings and among a patient's providers (consistent with privacy and security rules)—is integrally connected to reforming health care payment systems to shift from volume-driven to value-driven payment models. We expect that most value-based arrangements would involve activities that coordinate and manage the care of a target patient population, but did not propose to limit the universe of compensation arrangements that will qualify as value-based arrangements to those arrangements specifically for the coordination and management of patient care. Rather, we sought comment on our approach and whether we should revise the definition of ''value-based arrangement'' to require care coordination and management in order to qualify as a value-based arrangement. As discussed in more detail later in this section, the final definition of ''value-based arrangement'' does not require care coordination and management in order to qualify as a value-based arrangement; therefore, we are not including a corollary definition of ''care coordination and management'' in our final regulations.

The final exceptions at § 411.357(aa) apply only to value-based arrangements, the only parties to which, as described previously, are a value-based enterprise and one or more of its VBE participants or VBE participants in the same value-based enterprise. At final § 411.351, value-based enterprise is defined to mean two or more VBE participants: (1) Collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). A ''value-based enterprise'' includes only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value-based health care delivery and payment system. As we stated in the proposed rule, an ''enterprise'' may be a distinct legal entity—such as an ACO—with a formal governing body, operating agreement or bylaws, and the ability to receive payment on behalf of its affiliated health care providers (84 FR 55774). An ''enterprise'' may also consist only of the two parties to a value-based arrangement with the written documentation recording the arrangement serving as the required governing document that describes the enterprise and how the parties intend to achieve its value-based purpose(s). Whatever its size and structure, a value-based enterprise is essentially a network of participants (such as clinicians, providers, and suppliers) that have agreed to collaborate with regard to a target patient population to put the patient at the center of care through care coordination, increase efficiencies in the delivery of care, and improve outcomes for patients. The definition of ''value-based enterprise'' finalized at § 411.351 is focused on the functions of the enterprise, as it is not our intention to dictate or limit the appropriate legal structures for qualifying as a value-based enterprise.

To qualify as a value-based enterprise, among other things, each participant in the enterprise, whom we refer to as a VBE participant, must be a party to at least one value-based arrangement with at least one other participant in the enterprise. If a value-based enterprise is comprised of only two VBE participants, they must have at least one value-based arrangement with each other in order for the enterprise to qualify as a value-based enterprise. (Provided that a value-based enterprise exists, an arrangement between the enterprise and a physician who is a VBE participant in the value-based enterprise may qualify as a ''value-based arrangement'' for purposes of the exceptions at § 411.357(aa) if the value-based enterprise is itself an ''entity'' as defined at § 411.351.) In addition, a value-based enterprise must have an accountable body or person that is responsible for the financial and operational oversight of the enterprise. This may be the governing board, a committee of the governing board, or a corporate officer of the legal entity that is the value-based enterprise, or this may be the party to a value-based arrangement that is designated as being responsible for the financial and operational oversight of the arrangement between the parties (for example, if the ''enterprise'' consists of just the two parties). Finally, a value-based enterprise must have a governing document that describes the enterprise and how its VBE participants intend to achieve its value-based purpose(s). Implicit in this requirement is that the value-based enterprise must have at least one value-based purpose.

Also critical to qualifying as a value-based arrangement are the scope and objective of the arrangement. As noted previously, only an arrangement for activities that are reasonably designed to achieve at least one of the value-based enterprise's value-based purposes may qualify as a value-based arrangement to which the exceptions at § 411.357(aa) apply. At final § 411.351, value-based purpose is defined to mean: (1) Coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population. As we stated in the proposed rule, some of these goals are recognizable as part of the successor frameworks to the ''triple aim'' that are integral to CMS' value-based programs and our larger quality strategy to reform how health care is delivered and reimbursed (84 FR 55774). Our definition of ''value-based purpose'' identifies four core goals related to a target patient population. One or more of these goals must anchor the activities underlying every compensation arrangement that qualifies as a value-

[4] For purposes of this section, the term ''providers'' includes both providers and suppliers as those terms are defined in 42 CFR 400.202, as well as other components of the health care system. The term is used generically unless otherwise noted.

based arrangement to which the exceptions at final § 411.357(aa) apply.

In the proposed rule, we sought comment on whether it would be desirable or necessary to codify in regulation text what is meant by ''coordinating and managing care'' and, if so, whether ''coordinating and managing care'' should be defined to mean the deliberate organization of patient care activities and sharing of information between two or more VBE participants, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population (84 FR 55775). This definition was intended to correspond to a similar definition proposed by OIG. As described in more detail below, we are not finalizing a definition of ''coordinating and managing care'' in our regulations. We also sought comment regarding whether additional interpretation of the other proposed value-based purposes is necessary, but did not receive comments on the need for additional interpretation of any other aspect of the definition of ''value-based purpose.'' We respond to comments on this topic below.

We proposed to define VBE participant (that is, a participant in a value-based enterprise) to mean an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. We noted in the proposed rule that the word ''entity,'' as used in the definition of ''VBE participant,'' is not limited to non-natural persons that qualify as ''entities'' as defined at § 411.351 (84 FR 55775). We proposed to use the word ''entity'' in the definition of ''VBE participant'' in order to align with the definition proposed by OIG. We sought comment regarding whether the use of the word ''entity'' in this definition would cause confusion due to the fact that the universe of non-natural persons (that is, entities) that could qualify as VBE participants is greater than the universe of non-natural persons that qualify as ''entities'' under § 411.351 and, if so, what alternatives exist for defining ''VBE participant'' for purposes of the physician self-referral law. As discussed in more detail below, we are modifying the definition of VBE participant in this final rule to mean a *person or entity* that engages in at least one value-based activity as part of a value-based enterprise. The phrase ''person or entity'' is used more frequently throughout our regulations and, even though the word ''entity'' (as included in the definition of ''VBE participant'') is not limited to an ''entity'' as defined at § 411.351 and its use could result in some confusion for stakeholders, we believe that it is less disruptive to use the already-common phrase ''person or entity'' to define VBE participant. We may consider whether to replace the word ''entity'' throughout our regulations in those instances where it is not intended to be limited to the defined term at § 411.351. However, any revisions to our regulations to achieve this substitution would occur through future notice-and-comment rulemaking.

In the proposed rule, we also discussed the experiences of our law enforcement partners, including oversight experience, and the resulting concern about protecting potentially abusive arrangements between certain types of entities that furnish designated health services for purposes of the physician self-referral law (84 FR 55775). Specifically, we discussed concerns about compensation arrangements between physicians and laboratories or suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that may be intended to improperly influence or capture referrals without contributing to the better coordination of care for patients (84 FR 55776). We stated that we were considering whether to exclude laboratories and DMEPOS suppliers from the definition of VBE participant or, in the alternative, whether to include in the exceptions at § 411.357(aa), a requirement that the arrangement is not between a physician (or immediate family member of a physician) and a laboratory or DMEPOS supplier. We also stated that, in particular, we were uncertain as to whether laboratories and DMEPOS suppliers have the direct patient contacts that would justify their inclusion as parties working under a protected value-based arrangement to achieve the type of patient-centered care that is a core tenet of care coordination and a value-based health care system. In addition, due to our (and our law enforcement partners') ongoing program integrity concerns with certain other participants in the health care system and to maintain consistency with policies proposed by OIG, we stated that we were also considering whether to exclude the following providers, suppliers, and other persons from the definition of ''VBE participant'': Pharmaceutical manufacturers; manufacturers and distributors of DMEPOS; pharmacy benefit managers (PBMs); wholesalers; and distributors. At final § 411.351, ''VBE participant'' is defined to mean a person or entity that engages in at least one value-based activity as part of a value-based enterprise. The definition of ''VBE participant'' finalized here does not exclude any specific persons, entities, or organizations from qualifying as a VBE participant.

Lastly, we are finalizing the definition of ''target patient population'' as proposed, without modification. Specifically, the target patient population for which VBE participants undertake value-based activities is defined at final § 411.351 to mean an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that: (1) Are set out in writing in advance of the commencement of the value-based arrangement; and (2) further the value-based enterprise's value-based purpose(s). We affirm in this final rule that legitimate and verifiable criteria may include medical or health characteristics (for example, patients undergoing knee replacement surgery or patients with newly diagnosed type 2 diabetes), geographic characteristics (for example, all patients in an identified county or set of zip codes), payor status (for example, all patients with a particular health insurance plan or payor), or other defining characteristics. As we stated in the proposed rule, selecting a target patient population consisting of only lucrative or adherent patients (cherry-picking) and avoiding costly or noncompliant patients (lemon-dropping) would not be permissible under most circumstances, as we would not consider the selection criteria to be legitimate (even if verifiable) (84 FR 55776).

We received comments on the proposed definitions of value-based activity, value-based arrangement, value-based enterprise, value-based purpose, VBE participant, and target patient population. Our responses follow.

Comment: Most commenters supported our proposed definition of value-based activity, but many requested further guidance regarding what CMS would consider appropriate value-based activities. Specifically, some commenters asked whether particular items or services, such as transportation services or the provision of non-medical personnel, would qualify as value-based activities. Commenters did not explain how the arrangements for those particular items or services would implicate the physician self-referral law; that is, whether the items or services are in-kind remuneration provided by an entity to a physician or an immediate family member of a physician under an arrangement between a physician (or

immediate family member of a physician), whether the items or services are provided by one of the parties to a value-based arrangement and paid for by the recipient of the items or services, or whether the services are provided to patients.

Response: We decline to provide a list of items or services, actions, and ways to refrain from taking an action that qualify as value-based activities. We are concerned that even a non-exhaustive list of common value-based activities could unintentionally limit innovation and inhibit robust participation in value-based health care delivery and payment systems. The final definition of ''value-based activity'' provides the flexibility for parties to design arrangements that further the value-based purpose(s) of value-based enterprises. The determination regarding whether the provision of an item or service, the taking of an action, or the refraining from taking an action constitutes a value-based activity is a fact-specific analysis and turns on whether the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise.

With respect to the examples provided by the commenters, we note that the scope of the physician self-referral law is limited to a financial relationship between a physician (or the immediate family member of a physician) and the entity to which the physician makes referrals for designated health services. We assume that the commenters were referring to the provision of transportation services to a beneficiary, which would not implicate the law unless the beneficiary was a physician or an immediate family member of a physician. With respect to the commenters' inquiry regarding the provision of non-medical personnel, assuming that the commenters were referring to the provision of non-medical personnel to a physician by an entity, we are uncertain whether the commenter is referring to in-kind remuneration between an entity and a physician in the form of the services of non-medical personnel without expectation of payment or whether the provision of non-medical personnel would be paid for in cash under the terms of an arrangement between an entity and a physician. Therefore, we are unable to provide specific guidance in response to the inquiry.

Comment: A few commenters requested guidance on what it means for a value-based activity to be reasonably designed to achieve at least one value-based purpose. Some of the commenters expressed concern that our solicitation of comments in the proposed rule could be interpreted to signal that success is required in order for the protections of the value-based exceptions to apply, noting that success of a value-based activity in achieving the intended value-based purpose is never guaranteed. One of the commenters urged CMS to confirm that ''satisfying the value-based purposes element of various value-based definitions does not necessarily mean actual success in achieving the purposes but means engaging in collaboration and activities 'reasonably designed to achieve' one or more of these value-based purposes.''

Response: The determination regarding whether a value-based activity is reasonably designed to achieve at least one value-based purpose is a fact-specific determination. Parties must have a good faith belief that the value-based activity will achieve or lead to the achievement of at least one value-based purpose of the value-based enterprise in which the parties to the arrangement are VBE participants. We recognize that parties may undertake activities that do not ultimately achieve the value-based purpose(s) of the enterprise. Nothing in our final regulations requires that the value-based purpose(s) must be achieved in order for a value-based arrangement to be protected under an applicable exception at § 411.357(aa). However, if the parties are aware that the provision of the item or service, the taking of the action, or the refraining from taking the action will not further the value-based purpose(s) of the value-based enterprise, it will cease to qualify as a value-based activity and the parties may need to amend or terminate their arrangement. As discussed in section II.A.2.b.(3). of this final rule, we are including a requirement in the final exception for value-based arrangements at § 411.357(aa)(3)(vii) that parties must monitor whether they have furnished the value-based activities required under the arrangement and whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise.

Comment: A few commenters requested guidance on how parties can document or otherwise show that a value-based activity is ''reasonably designed'' to achieve a value-based purpose.

Response: We do not dictate how parties should analyze the design of their value-based arrangements to ensure that the value-based activities they undertake are reasonably designed to achieve at least one value-based purpose of the value-based enterprise of which they are participants or how they should substantiate their efforts. We note that contemporaneous documentation is a best practice, and we encourage parties to follow this practice. We also remind parties that the burden of proof to show compliance with the physician self-referral law is set forth at § 411.353 and is applicable to parties utilizing the new exceptions for value-based arrangements at final § 411.357(aa). We emphasize that the new exceptions do not impose an additional or different burden of proof. It is the responsibility of the entity submitting a claim for payment for designated health services furnished pursuant to a referral from a physician with which it has a financial relationship to ensure compliance with the physician self-referral law at the time of submission of the claim. That is, parties must ensure that their financial relationship satisfies all the requirements of an applicable exception at the time the physician makes a referral for designated health service(s).

Comment: Several commenters expressed concern with our statement that the making of a referral is not a value-based activity and requested that CMS revise the definition of value-based activity to include the making of a referral. These commenters noted that the definition of ''referral'' at § 411.351 includes the establishment of a plan of care that includes the provision of designated health services. The commenters also asserted that referrals are an integral part of a value-based health care delivery and payment system, especially with respect to care planning, and contended that excluding the making of a referral from the definition of ''value-based activity'' would significantly limit the utility of the exceptions. Some commenters urged CMS to revise the definition of ''value-based activity'' to specifically *include* the making of a referral as a value-based activity.

Response: The commenters raise important points about the scope of the definition of ''referral'' at § 411.351 and the exclusion of the making of a referral from the definition of ''value-based activity.'' It was not our intention to exclude the development of a care plan that includes the furnishing of designated health services from the definition of ''value-based activity.'' Accordingly, we are not finalizing the reference to the making of a referral in the definition of ''value-based activity.'' We are defining value-based activity to mean any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) The provision of an item

or service; (2) the taking of an action; or (3) the refraining from taking an action. Care planning activities that meet the definition of ''referral'' at § 411.351 will qualify as ''the taking of an action'' for purposes of applying the definition of ''value-based activity.'' As discussed in section II.D.2.c. of this final rule, we are revising the definition of ''referral'' at § 411.351 to codify in regulation text our policy that a referral is not an item or service for purposes of section 1877 of the Act and the physician self-referral law regulations.

Comment: Most commenters supported the proposed definition of ''value-based arrangement.'' However, a few commenters requested that we expand the definition to specifically include the following alternative payment models (APMs): Advanced APMs, all-payor/other-payor APMs, and Merit-based Incentive Payment System (MIPS) Alternative Payment Models (APMs) under the Quality Payment Program (QPP). The commenters also requested that we include State-based Medicaid initiatives in the definition of ''value-based arrangement.''

Response: We decline to adopt the commenters' suggestion and are finalizing the definition as proposed. The models referenced by the commenters relate to value-based payments from a payor to a physician under a payment arrangement between the payor and the physician. For purposes of the physician self-referral law, a compensation arrangement is an arrangement between a physician (or immediate family member of a physician) and the entity to which the physician makes referrals for designated health services. The definition of ''value-based arrangement'' relates to a compensation arrangement between a physician and an entity that participate in the same value-based enterprise. It does not cover compensation arrangements between a payor and a physician.

Comment: Most commenters generally supported our proposed definition of ''value-based enterprise,'' although one commenter had concerns with the requirement that each VBE participant must be a party to a value-based arrangement with at least one other VBE participant in the value-based enterprise. This commenter interpreted this requirement to preclude the addition of VBE participants to a value-based arrangement after the value-based arrangement has begun. The commenter requested that we permit parties to add VBE participants to a value-based arrangement throughout the duration of the arrangement, either on an ongoing basis or at least annually.

Response: The design and structure of contracts is separate and distinct from the analysis of financial relationships under the physician self-referral law. Although nothing in our regulations prohibits having multiple parties to a contract or adding parties after the effective date of the contract, each of the financial relationships that results from the contract must be analyzed separately under the physician self-referral law. The commenter described adding new physicians to an existing value-based arrangement. For purposes of determining compliance with the physician self-referral law, an arrangement between an entity and a ''new'' physician engaging in value-based activities will not be viewed as an ''addition'' to an existing value-based arrangement but, rather, a separate and distinct compensation arrangement that must be analyzed for compliance with an applicable exception. To illustrate, assume that a hospital and a physician organization enter into a value-based arrangement under which the physician organization agrees that all its physicians will abide by the hospital's care protocols for a period of 2 years. During the course of the value-based arrangement, the physician organization hires a new physician who agrees to abide by the hospital's care protocols as called for by the physician organization's arrangement with the hospital. Assuming the new physician stands in the shoes of the physician organization under § 411.354(c), the ''addition'' of the new physician to the physician organization creates a separate new financial relationship between the hospital and the new physician that must satisfy the requirements of an applicable exception to the physician self-referral law. Nothing in the definition of ''value-based enterprise'' will preclude a new VBE participant from providing value-based activities and participating in a value-based arrangement with another VBE participant or the value-based enterprise itself (if the value-based enterprise is an entity for purposes of the physician self-referral law).

Comment: Many commenters sought additional guidance regarding the type of organized network or group of persons or entities that may qualify as a value-based enterprise.

Response: A value-based enterprise may be a distinct legal entity—such as an ACO—with a formal governing body, operating agreement or bylaws, and the ability to receive payment on behalf of its affiliated health care providers and suppliers. A value-based enterprise may also be an informal affiliation, even consisting of only the two parties to a value-based arrangement. The definition of ''value-based enterprise'' is intended to include only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value-based health care delivery and payment system. Whatever its size and structure, a value-based enterprise is essentially a network of participants (such as clinicians, providers, and suppliers) that have agreed to collaborate with regard to a target patient population to put the patient at the center of care through care coordination, increase efficiencies in the delivery of care, and improve outcomes for patients. Simply stated, a value-based enterprise is a network of individuals and entities that are collaborating to achieve one or more value-based purposes of the value-based enterprise. We do not believe that it would be beneficial to dictate particular legal or other structural requirements for a value-based enterprise. Rather, the definition of ''value-based enterprise'' is intended to encompass a wide-range of structures to help facilitate health care providers' transition to a value-based health care delivery and payment system.

Comment: A few commenters requested guidance with respect to the requirement that the value-based enterprise have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise, specifically with respect to the responsibilities, requirements, structure, and composition of the accountable body. One commenter requested confirmation that an ACO could rely on its existing governing body and would not need to establish a separate accountable body or identify a person other than the ACO's governing body to be responsible for the financial and operational oversight of the value-based enterprise. Several commenters expressed concern that requiring one individual or entity to assume responsibility for the financial and operational oversight of the value-based enterprise could create tension between VBE participants and limit the utility of the exceptions for smaller value-based enterprises. Other commenters asserted that the establishment of the accountable body or person and the development of the governing document would require the expenditure of significant resources, including legal expenses, and questioned whether this burden is necessary. One of these commenters suggested that this requirement is especially burdensome for small or rural practices that may not

have sufficient resources to satisfy the requirement. Some commenters also requested explicit guidance regarding the governing document that describes the value-based enterprise and how its VBE participants intend to achieve the enterprise's value-based purpose(s).

Response: Transparency and accountability are critical to a successful transition to a value-based health care delivery and payment system. It is essential that CMS and our law enforcement partners are able to identify the person or organization ultimately responsible for the financial and operational oversight of a value-based enterprise. We do not believe that requiring a value-based enterprise to have an accountable body or responsible person and a governing document creates an administrative or financial burden beyond what parties that wish to transition to value-based health care would already incur.

We are not persuaded to abandon the requirement that a value-based enterprise must have an accountable body or person that is responsible for the financial and operational oversight of the enterprise. As discussed in the proposed rule and as noted above, the accountable body or person that is responsible for the financial and operational oversight of the enterprise may be the governing board, a committee of the governing board, or a corporate officer of the legal entity that is the value-based enterprise, or may be the party to a value-based arrangement that is designated as being responsible for the financial and operational oversight of the arrangement between the parties (if the ''enterprise'' is a network consisting of just the two parties) (84 FR 55774). We expect that a value-based enterprise would establish an accountable body or designate a responsible person commensurate with the scope and objectives of the value-based enterprise and its available resources.

We are also maintaining the requirement that the enterprise must have a governing document that describes the value-based enterprise and how its VBE participants intend to achieve its value-based purpose(s). Parties regularly enter into payor contracts, employment relationships, service arrangements, and other arrangements for items and services related to the provision of patient care services. It is a matter of general contracting practice that these contracts and written agreements specify the rights, responsibilities, and obligations of the parties. We expect that independent health care providers that wish to organize and collaborate to achieve value-based purposes would utilize these same basic practices to reduce their arrangements to writing, including their arrangement to form a value-based enterprise. We believe that the same is true for the development of a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). We remind parties that we are not dictating particular legal or other structural requirements for a value-based enterprise; rather, the final regulations accommodate both formal and informal value-based enterprises. As a result, the written agreements and contracts that parties enter into in the normal course of their business dealings could serve as the documentation required under the new exception for value-based arrangements.

It is simply not possible to establish one set of financial and operational oversight requirements that would be applicable to value-based enterprises of all types and sizes. The financial and operational oversight of a value-based enterprise and the related governing document for a value-based enterprise made up of only a hospital and physician will look very different from that of an ACO that contracts with thousands of providers and suppliers. Again, we do not dictate the structure or composition of the accountable body; rather, we simply require that the accountable body or responsible person for the value-based enterprise exercise appropriate financial and operational oversight of the value-based enterprise. Similarly, we do not dictate the format or content of the governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). The necessary infrastructure to effectively oversee the financial and operational activities of the value-based enterprise and the governing document will depend on the size and structure of the value-based enterprise.

Comment: Several commenters recommended that CMS not limit the types of entities that may qualify as a VBE participant out of concern that any such limitations could slow down or inhibit the movement of the entire health care industry towards value-based health care delivery and significantly limit the utility of the exceptions. The commenters provided detailed examples of how laboratories and DMEPOS suppliers, in particular, contribute to the value-based health care delivery and payment system by collaborating with other sectors of the health care industry to improve care, lower costs, and ensure that patients are receiving appropriate care. Other commenters expressed concern that the exclusion of laboratories and DMEPOS suppliers from participation in value-based enterprises would impact the ability of health systems that own laboratories or DMEPOS suppliers from participating in value-based health care delivery.

Response: We are not excluding any specific persons, entities, or organizations from the definition of ''VBE participant.'' We find the commenters' assertions that laboratories and DMEPOS suppliers may play a beneficial role in the delivery of value-based health care persuasive. However, we will continue to monitor the evolution of the value-based health care delivery and payment system to ensure that the inclusion of all types of providers and suppliers as VBE participants does not create a program integrity risk.

Comment: A number of commenters supported the inclusion of coordinating and managing the care of a target patient population as an appropriate value-based purpose, although the majority of these commenters urged CMS to not define ''coordinating and managing care'' in regulation text, suggesting that the phrase is self-explanatory and defining it could inadvertently limit or interfere with innovation. Commenters that were open to the inclusion of a definition of ''coordinating and managing care'' stressed the need for any such definition to be drafted broadly. Other commenters suggested that, if we codify a definition of ''coordinating and managing care,'' it should align with any definition of the same term adopted by OIG.

Response: We agree with the commenters that it is not necessary to define ''coordinating and managing care'' for purposes of the definition of ''value-based purpose.'' In addition, we do not believe that it is necessary to define ''coordinating and managing care'' for purposes of the exceptions finalized at § 411.357(aa), as they are not limited only to value-based arrangements for the coordination or management of care.

Comment: Many commenters requested that we include as a value-based purpose the maintenance of quality of care for the target population without requiring a reduction in costs to payors.

Response: We decline to include the maintenance of quality of care as a permissible value-based purpose in the absence of reduction of the costs to or growth in expenditures of payors. Although we recognize that the maintenance of quality of care may advance the goals of a value-based

enterprise or the specific parties to a value-based arrangement, we do not believe that the maintenance of quality of care in the absence of a reduction in the costs to or growth in expenditures of payors advances the goals of the Regulatory Sprint. Thus, it is not appropriate to include the maintenance of quality of care as a stand-alone value-based purpose that would unlock access to the exceptions at § 411.357(aa). We note that numerous CMS programs and Medicare payment mechanisms already require the maintenance of quality across the care continuum and encourage improvement and maintenance of quality through use of payment incentives and payment reductions. For example, under the Hospital Inpatient Quality Reporting Program, CMS collects quality data from hospitals paid under the IPPS. Data for selected measures are used for paying a portion of hospitals based on the quality and efficiency of care, including the Hospital-Acquired Condition Reduction Program, Hospital Readmissions Reduction Program, and Hospital Value-Based Purchasing Program, which rewards acute care hospitals with incentive payments based on the quality of care they provide, rather than just the quantity of services they provide.

Comment: The majority of commenters supported the definition of ''value-based purpose'' and urged CMS to finalize the definition without modifications. A few commenters requested that we revise the definition of ''value-based purpose'' to include the reduction in costs to or growth in expenditures of *health care providers and suppliers.* These commenters asserted that limiting the definition of value-based purpose to reducing the costs to or growth in expenditures of only payors fails to recognize the benefits to Medicare that come from the reduction of provider costs, such as reporting lower costs to Medicare on the hospital's cost report, which, in turn, result in lower Medicare expenditures. These commenters pointed to internal cost savings programs that distribute savings generated from implementing specific cost saving measures to physicians. The commenters expressed concern that hospital-initiated quality and efficiency programs that drive down hospital costs, improve efficiency, and improve quality of care would not be protected by the exceptions because the hospital's program would not directly reduce costs to or growth in expenditures of payors.

Response: We are not persuaded to revise the definition of ''value-based purpose'' as requested by the commenters. We believe that the four purposes included in the definition are sufficiently inclusive to allow for innovative value-based arrangements while protecting against program or patient abuse. We do not believe that permitting a value-based enterprise to exist solely for the purpose of reducing costs to its VBE participants would adequately protect the Medicare program and its beneficiaries from abuse. Moreover, allowing parties to share in the reduction of costs without also improving or maintaining quality of care for patients or otherwise benefitting payors does not advance the transition to a value-based health care delivery and payment system. We note that nothing in this final rule precludes the sharing of cost savings and other entity-specific savings programs, provided those programs are part of a value-based arrangement for value-based activities reasonably designed to further at least one value-based purpose of the value-based enterprise of which the parties to the arrangement are VBE participants. The compensation to a physician under such a value-based arrangement could include a share of the savings that result from a hospital's internal cost sharing (or gainsharing) program.

Comment: A few commenters specifically supported the inclusion as a value-based purpose ''transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.'' These commenters stated that allowing a value-based enterprise to operate for this purpose is necessary to achieve CMS' goal of transitioning to a value-based health care delivery and payment system and strikes the right balance between precision and flexibility. The commenters asserted that value-based enterprises would rely on this purpose to cover the clinical integration and infrastructure activities necessary to develop and implement a value-based enterprise and to meet future operational and capital requirements. Commenters likened this value-based purpose to the purpose underlying the pre-participation waiver for the Shared Savings Program. The commenters recommended that we make no further refinement to this value-based purpose.

Response: The commenters' understanding of the scope of this value-based purpose is correct. As we discussed in the proposed rule, this value-based purpose is intended to accommodate efforts aimed at transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for the target patient population (84 FR 55775). Generally speaking, we interpret ''transitioning'' to mean undergoing the process or period of transition from one state or condition to another and, specifically, with respect to this value-based purpose, the process or period of transition from furnishing patient care services in a FFS volume-based system to furnishing patient care services in a value-based health care delivery and payment system. Thus, this value-based purpose applies during the period of a value-based enterprise's start-up or preparatory activities. In the proposed rule, we interpreted this value-based purpose as a category that includes the integration of VBE participants in team-based coordinated care models, establishing the infrastructure necessary to provide patient-centered coordinated care, and accepting (or preparing to accept) increased levels of financial risk from payors or other VBE participants in value-based arrangements (84 FR 55775). This purpose will also apply to activities undertaken by an unincorporated value-based enterprise that wishes to formalize its legal and operational structure, as well as the preparation by a value-based enterprise to accept financial risk and the preparation of VBE participants to furnish services in a manner focused on the value of those services instead of volume.

We agree that this value-based purpose shares certain aspects of the pre-participation waiver under the Shared Savings Program. In our discussion of the Shared Savings Program pre-participation waiver in our October 29, 2015 Shared Savings Program Final Waivers in Connection with the Shared Savings Program Final Rule (80 FR 66726) (the SSP waivers final rule), we provided examples of start-up arrangements as guideposts for determining whether a particular arrangement may qualify for protection under the pre-participation waiver (80 FR 66733). We believe those examples, to the extent they create a compensation relationship for purposes of the physician self-referral law, may be illustrative for purposes of interpreting the scope of ''transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.'' In the SSP waivers final rule (80 FR 66733), we stated that the following types of start-up arrangements

may qualify under the Shared Savings Program pre-participation waiver:

- Infrastructure creation and provision.
- Network development and management, including the configuration of a correct ambulatory network and the restructuring of existing providers and suppliers to provide efficient care.
- Care coordination mechanisms, including care coordination processes across multiple organizations.
- Clinical management systems.
- Quality improvement mechanisms including a mechanism to improve patient experience of care.
- Creation of governance and management structure.
- Care utilization management, including chronic disease management, limiting hospital readmissions, creation of care protocols, and patient education.
- Creation of incentives for performance-based payment systems and the transition from fee-for-service payment system to one of shared risk of losses.
- Hiring of new staff, including care coordinators (including nurses, technicians, physicians, and/or non-physician practitioners), umbrella organization management, quality leadership, analytical team, liaison team, IT support, financial management, contracting, and risk management.
- IT, including EHR systems, electronic health information exchanges that allow for electronic data exchange across multiple platforms, data reporting systems (including all payor claims data reporting systems), and data analytics (including staff and systems, such as software tools, to perform such analytic functions).
- Consultant and other professional support, including market analysis for antitrust review, legal services, and financial and accounting services.
- Organization and staff training costs.
- Incentives to attract primary care physicians.
- Capital investments, including loans, capital contributions, grants, and withholds.

Many of these activities similarly facilitate a value-based enterprise's (and its VBE participants') transition from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Comment: We received a number of comments regarding the selection criteria that may be used to choose a target patient population and, specifically, what it means for selection criteria to be legitimate and verifiable. Although several commenters supported the standard that selection criteria must be legitimate and verifiable, stating that it struck the right balance between encouraging innovation and protecting against fraud and abuse, other commenters expressed concern with the use of the term ''legitimate,'' asserting that it is ambiguous and may expose parties to litigation and enforcement risk. Some commenters requested that we instead prohibit the specific selection criteria that we believe are inappropriate, such as cherry-picking and lemon-dropping, while others requested that we provide a list of selection criteria that would be deemed permissible. A few commenters asked whether specific selection criteria would be acceptable, such as identifying the target patient population by the MS–DRG assigned to the patient, geography, demographic criteria (for example, age or socioeconomic status), or payor (for example, Medicaid or non-Federal payor).

Response: At final § 411.351, ''target patient population'' means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s). We do not believe that it is necessary to further define the term ''legitimate.'' It has been used throughout the physician self-referral regulations for decades. For example, the exception for personal service arrangements includes a requirement at § 411.357(d)(1)(iii) that the aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. The term ''legitimate'' does not carry a new or different definition for purposes of interpreting the value-based definitions or the exceptions at § 411.357(aa). We refer readers to section II.B.2. of this final rule for further discussion of the term ''legitimate'' within our regulations. With respect to the commenters' requests for lists of impermissible and permissible selection criteria, it is not feasible to provide such an exhaustive list of selection criteria that we consider unacceptable. Similarly, we believe that providing a list of acceptable selection criteria could serve to interfere with or limit a value-based enterprise's or VBE participant's ability to identify and utilize selection criteria. Deeming provisions sometimes have a chilling effect because they are, in practice, interpreted by the regulated industry as mandatory or otherwise prescriptive rules. We believe the approach we have finalized balances the need for clear guidelines with the need for flexibility. Finally, with respect to the commenters' request for confirmation that specific selection criteria are permissible, we reiterate that the determination whether the selection criteria used to identify a target patient population are legitimate and verifiable is dependent on the facts and circumstances of the parties. If the criteria are selected primarily for their effect on the parties' profits or purely financial concerns, they will not be considered legitimate and, therefore, are impermissible. None of the selection criteria examples shared by the commenters are *per se* impermissible.

Comment: Some commenters expressed concern with our statement in the proposed rule that choosing a target patient population in a manner driven by profit motive or purely financial concerns would not be legitimate (84 FR 55776). These commenters suggested that this calls into question proven cost-saving techniques, such as product standardization, aimed at reductions in cost or unnecessary care that impact financial performance. The commenters requested that CMS clarify the distinction between reducing costs and problematic criteria, and asked us to explicitly acknowledge that it is permissible to choose a target patient population that could generate cost reductions from activities like product standardization alone.

Response: It appears to us that these commenters have conflated the acceptable criteria for selecting a target patient population and the requirements for selecting activities to be performed under a value-based arrangement. The target patient population is the group of individuals for whom the parties to a value-based arrangement are undertaking value-based activities. Our statement regarding profit motive or purely financial concerns relates to choosing the patient population for which the parties will undertake value-based activities and not the value-based activities themselves. We reiterate that the selection of the target patient population may not be driven by profit motive or purely financial concerns. As we stated in the proposed rule, selecting a target patient population consisting of only lucrative or adherent patients (cherry-picking) and avoiding costly or noncompliant patients (lemon-dropping) would not be permissible under most circumstances, as we will not consider the selection criteria to be

legitimate (even if verifiable) (84 FR 55776). Choosing a target patient population solely because it appears likely to reduce the costs to one of the parties to a value-based arrangement would be suspect. As described earlier in this section and in our response to other comments, a value-based activity must be reasonably designed to achieve at least one value-based purpose of the value-based enterprise. With respect to the commenter's specific inquiry, we note that a value-based activity that requires a physician to utilize a standardized list of products, where appropriate, may be reasonably designed to achieve at least one value-based purpose of the value-based enterprise, depending on the enterprise's value-based purposes.

Comment: A large number of commenters expressed concern with a requirement that the patients in the target patient population have at least one chronic condition to be addressed by the value-based arrangement and urged CMS to not limit the target patient population to chronic patients. The commenters stated that such a requirement would severely constrict the types of value-based arrangements protected under the new exceptions.

Response: Although we sought comment as to whether we should incorporate a requirement that patients in the target patient population have at least one chronic condition in order to align with OIG's proposals, we are not including this provision in the final definition of ''target patient population'' at § 411.351. As finalized, target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s). We are not limiting a target patient population to patients with at least one chronic condition.

Comment: A few commenters requested clarification that the definition of ''target patient population'' would include patient populations that are retroactively attributed, noting as an example the use of a retrospective claims-based methodology.

Response: A target patient population must be selected based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement. The commenter's concerns appear to relate to the requirement that selection criteria for the target patient population must be set out in writing in advance of the commencement of the value-based arrangement. Where a target patient population is ascribed to the value-based enterprise (or the VBE participants that are parties to the specific value-based arrangement) by the payor, the payor establishes the criteria for selecting the target patient population. However, this does not affect the obligation of the value-based enterprise or its VBE participants to select the target patient population for purposes of the physician self-referral law and qualification to use the exceptions at § 411.357(aa). The definition of ''target patient population'' at final § 411.351 requires that the target patient population is selected by the value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement under which value-based activities are undertaken for the target patient population and that further the value-based enterprise's value-based purpose(s). Thus, where a target patient population is ascribed to the value-based enterprise (or the VBE participants that are parties to the specific value-based arrangement) by the payor, the value-based enterprise or its VBE participants must ensure that the requirements of the definition of ''target patient population'' are satisfied.

In the circumstances described by the commenters, the selection criteria for the target patient population could be described as ''the target patient population to be identified by the payor in accordance with criteria established by the payor for retrospective attribution.'' The value-based enterprise or the VBE participants that are parties to the specific value-based arrangement under which value-based activities are undertaken for the target patient population must ensure that the payor's methodology for attribution of the target patient population are legitimate and verifiable and that they will further the value-based enterprise's value-based purpose(s). In addition, the selection criteria must be documented in advance of the commencement of the value-based arrangement. It is not sufficient for the value-based enterprise or its VBE participants to merely state that the selection criteria will be determined by another party (in this case, the payor). The value-based enterprise or its VBE participants may need to collaborate with the payor to ensure that the patient population attributed meets the definition of ''target patient population.''

Comment: Most commenters supported the proposed definition of ''VBE participant.'' A few commenters objected to the use of the term ''entity'' in the definition of ''VBE participant,'' because the term ''entity'' is ascribed a specific meaning at § 411.351, but, as used in the definition of ''VBE participant,'' would not be limited to that meaning. Commenters noted that using the same term in two different ways within the same regulatory scheme creates unnecessary complexity and compliance concerns. Commenters sought clarity on this issue, and requested that we either revise the definition of ''entity'' at § 411.351 or use a different term for purposes of the definition of ''VBE participant.''

Response: Although we understand the commenter's concerns, we are not revising the definition of ''VBE participant'' to replace the term ''entity'' with another term, nor are we revising the definition of ''entity'' at § 411.351. In the physician self-referral regulations, the term ''entity'' is used to indicate an entity (as defined at § 411.351) furnishing designated health services and also to indicate its general meaning of an organization (such as a business) that has an identity separate from those of its members. As used in the final definition of ''VBE participant,'' the term ''entity'' is not limited to an entity furnishing designated health services. Rather, it has its general meaning.

Although we retain the term ''entity'' in the definition of ''VBE participant,'' we are replacing the term ''individual'' (as proposed) with the term ''person.'' Thus, under our final regulation, VBE participant means a person or entity that engages in at least one value-based activity as part of a value-based enterprise. We intend for ''person or entity'' to refer to both natural and non-natural persons. Again, the term ''entity'' in this context is not limited to an entity that furnishes designated health services. Our review of the physician self-referral regulations indicates that the term ''person or entity'' is used numerous times throughout the regulations. For example, as defined at § 411.351, a ''referring physician'' is a physician who makes a referral or who directs another *person or entity* to make a referral or who controls referrals made by another *person or entity.* The regulations regarding indirect compensation arrangements at § 411.354(c)(2) state that one element of an indirect compensation arrangement is that there exists between the referring physician (or a member of his or her immediate family member) and the entity furnishing designated health services an unbroken chain of any number (but not fewer than one) of *persons or entities* that have financial

relationships between them. The regulations also use this term in the context of the *person or entity* from whom the referring physician or immediate family member receives aggregate compensation under the arrangement. The exceptions for the rental of office space and the rental of equipment reference a *person or entity* in the exclusive use requirements at § 411.357(a)(3) and (b)(2). For consistency with our existing regulations, we are including the term ''person or entity'' in our final definition of ''VBE participant.''

b. Exceptions

The physician self-referral law (along with other Federal fraud and abuse laws) provides critical protection against a range of troubling patient and program abuses that may result from volume-driven, FFS payment. These abuses include unnecessary utilization, increased costs to payors and patients, inappropriate steering of patients, corruption of medical decision making, and competition based on buying referrals instead of delivering quality, convenient care. While value-based payment models hold promise for addressing these abuses, they may pose risks of their own, including risks of stinting on care (underutilization), cherry-picking, lemon-dropping, and manipulation or falsification of data used to verify outcomes. Moreover, during the transformation to value-based payment, many new delivery and payment models include both FFS and value-based payment mechanisms in the same model, subjecting providers to mixed incentives, and presenting the possibility of arrangements that pose both traditional FFS risk and emerging value-based payment risks.

When the physician self-referral law was expanded in 1993 to apply to designated health services beyond the clinical laboratory services to which the original 1989 law applied, according to the sponsor of the legislation, the Honorable Fortney ''Pete'' Stark, the physician self-referral law was intended to address physician referrals that drive up health care costs and result in unnecessary utilization of services. (*See* Opening Statement of the Honorable Pete Stark, Physician Ownership and Referral Arrangements and H.R. 345, ''The Comprehensive Physician Ownership and Referral Act of 1993,'' House of Representatives, Committee on Ways and Means, Subcommittee on Health, April 20, 1993, p. 144.) Mr. Stark went on to emphasize the importance of a physician's ability to offer patients neutral advice about whether or not services are necessary, which services are preferable, and who should provide them. He noted that the physician self-referral law would improve consumers' confidence in their physicians and the health care system generally. In other words, the legislation was proposed (and the law ultimately enacted) to counter the effects of physician decision making driven by financial self-interest—overutilization of health care services, the suppression of patient choice, and the impact on the medical marketplace.

As discussed in section I.B.2.a. of this final rule, in 1989 and 1993, the vast majority of Medicare services were reimbursed based on volume under a retrospective FFS system. The statutory exceptions to the physician self-referral law's referral and billing prohibitions were developed during this time of FFS, volume-based payment, with conditions which, if met, would allow the physician's ownership or investment interest or compensation arrangement to proceed without triggering the ban on the physician's referrals or the entity's claims submission. We believe that the exceptions in section 1877 of the Act indicate the Congress' stance on what safeguards are necessary to protect against program or patient abuse in a system where Medicare payment is available for each service referred by a physician and furnished by a provider or supplier. To date, the exceptions for compensation arrangements issued under section 1877(b)(4) of the Act, which grants the Secretary authority to establish exceptions for financial relationships that the Secretary determines do not pose a risk of program or patient abuse, have generally followed the blueprint established by the Congress for compensation arrangements that exist in a FFS system.

Value-based health care delivery and payment shifts the paradigm of our analysis under section 1877(b)(4) of the Act. When no longer operating in a volume-based system, or operating in a system that reduces the amount of FFS payment by combining it with some level of value-based payment, our exceptions need fewer ''traditional'' requirements to ensure the arrangements they protect do not pose a risk of program or patient abuse. This is because a value-based health care delivery and payment system, by design, provides safeguards against harms such as overutilization, care stinting, patient steering, and negative impacts on the medical marketplace. Using the Secretary's authority under section 1877(b)(4) of the Act, we are adding three exceptions for compensation arrangements that do not pose a risk of program or patient abuse when considered in concert with: (1) The program integrity and other requirements integrated in the definitions used to apply the exceptions only to compensation arrangements that qualify as ''value-based arrangements;'' and (2) the disincentives to perpetrate the harms the physician self-referral law was intended to deter that are intrinsic in the assumption of substantial downside financial risk and meaningful participation in value-based health care delivery and payment models.

In removing regulatory barriers to innovative care coordination and value-based arrangements, we are faced with the challenge of designing protection for emerging health care arrangements, the optimal form, design, and efficacy of which remains unknown or unproven. This is a fundamental challenge of regulating during a period of innovation and experimentation. Matters are further complicated by the substantial variation in care coordination and value-based arrangements contemplated by the health care industry, variation among patient populations and providers, emerging health technologies and data capabilities, and our desire not to chill beneficial innovations. Thus, a one-size-fits-all approach to protection from the physician self-referral law's prohibitions is not optimal. The design and structure of our exceptions are intended to further several complementary goals. First, we have endeavored to remove regulatory barriers, real or perceived, to create space and flexibility for industry-led innovation in the delivery of better and more efficient coordinated health care for patients and improved health outcomes. Second, consistent with the Secretary's priorities, the historical trend toward improving health care through better care coordination, and the increasing adoption of value-based models in the health care industry, the final exceptions are intended to create additional incentives for the industry to move away from volume-based health care delivery and payment and toward population health and other non-FFS payment models. In this regard, our exception structure incorporates additional flexibilities for compensation arrangements between parties that have increased their participation in mature value-based payment models and their assumption of downside financial risk under such models. As discussed in the proposed rule (84 FR 55776) and in more detail in this section II.A.2.b. of the final rule, our expectation is that meaningful assumption of downside financial risk would not only serve the overall transformation of industry payment systems, but could also curb, at

least to some degree, FFS incentives to order medically unnecessary or overly costly items and services, key patient and program harms addressed by the physician self-referral law (and other Federal fraud and abuse laws).

The current exceptions to the physician self-referral law include requirements that may create significant challenges for parties that wish to develop novel financial arrangements to facilitate their successful participation in health care delivery and payment reform efforts (84 FR 55776 through 55778). Most of the commonly relied upon exceptions to the physician self-referral law include requirements related to compensation that may be difficult to satisfy where the arrangement is designed to foster the behavior shaping necessary for the provision of high-quality patient care that is not reimbursed on a traditional FFS basis. Requirements that compensation be set in advance, fair market value, and not take into account the volume or value of a physician's referrals or the other business generated by the physician may inhibit the innovation necessary to achieve well-coordinated care that results in better health outcomes and reduced expenditures (or reduced growth in expenditures). For example, depending on their structure, arrangements for the distribution of shared savings or repayment of shared losses, gainsharing arrangements, and pay-for-performance arrangements that provide for payments to refrain from ordering unnecessary care, among others, may be unable to satisfy the requirements of an existing exception to the physician self-referral law. Thus, rather than being a check on bad actors, in the context of value-based care models, the physician self-referral law may actually be having a chilling effect on models and arrangements designed to bend the cost curve and improve quality of care to patients.

We have carefully considered the CMS RFI comments, the comments to the proposed rule, and anecdotal information shared by stakeholders regarding the impact of the specific requirements that compensation must be set in advance, fair market value, and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician, law enforcement and judicial activity related to these requirements, and our own observations from our work (including our work on fraud and abuse waivers for CMS accountable care and other models). We remain concerned that the inclusion of such requirements in the exceptions for value-based arrangements at § 411.357(aa) would conflict with our goal of addressing regulatory barriers to value-based care transformation. As discussed in more detail below, we are not including these requirements in the final exceptions for value-based arrangements at § 411.357(aa). We note that two of the final exceptions for value-based arrangements are available to protect arrangements even when payments from the payor are made on a FFS basis. Even so, we are not finalizing a requirement that remuneration is consistent with fair market value and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the entity. Instead, we are finalizing a carefully woven fabric of safeguards, including requirements incorporated through the applicable value-based definitions. The disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address that are built into the value-based definitions will operate in tandem with the requirements included in the exceptions and are sufficient to protect against program and patient abuse. This is especially true where a value-based enterprise assumes full or meaningful downside financial risk.

The beneficiary's right to choose a provider of care is expressed and reinforced in almost every aspect of the Medicare program. We believe that a patient's control over who provides his or her care directly contributes to improved health outcomes and patient satisfaction, enhanced quality of care and efficiency in the delivery of care, increased competition among providers, and reduced medical costs, all of which are aims of the Medicare program. Protection of patient choice is especially critical in the context of referrals made by a physician to an entity with which the physician has a financial relationship, as the physician's financial self-interest may impact, if not infringe on, patients' rights to control who furnishes their care. For this reason, we are making compliance with § 411.354(d)(4)(iv) a requirement of the exceptions that apply to employment arrangements, personal service arrangements, or managed care contracts that purport to restrict or direct physician referrals, including the exceptions at § 411.357(aa) for value-based arrangements. We are finalizing in all three exceptions at § 411.357(aa) a separate requirement to ensure that, regardless of the nature of the value-based arrangement and its value-based purpose(s), the regulation adequately protects a patient's choice of health care provider, the physician's medical judgment, and the ability of health insurers to efficiently provide care to their members. Specifically, even if the applicable exception at § 411.357(aa) does not require that the arrangement is set out in writing, any requirement to make referrals to a particular provider, practitioner, or supplier must be set out in writing and signed by the parties, and the requirement may not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

We believe that well-coordinated and managed patient care is the cornerstone of a value-based health care system. We solicited comments regarding whether it is necessary to include in the exceptions for value-based arrangements, a requirement that the parties to a value-based arrangement engage in value-based activities that include, at a minimum, the coordination and management of the care of the target patient population or that the value-based arrangement is reasonably designed, at a minimum, to coordinate and manage the care of the target patient population (84 FR 55780). We are not including such a requirement in the final exceptions at § 411.357(aa). In our experience, and as confirmed by commenters, most arrangements that qualify as value-based arrangements, by their nature, have care coordination and management at their heart, eliminating the need for an explicit requirement. Moreover, we remain concerned that requiring every value-based arrangement to include the coordination and management of care of the target patient population could leave beneficial value-based arrangements that do not directly coordinate or manage the care of the target patient population without access to any of the new exceptions at § 411.357(aa) and potentially unable to meet the requirements of any existing exception to the physician self-referral law.

Finally, we have endeavored to be as neutral as possible with respect to the types of value-based enterprises and value-based arrangements the final exceptions will cover in order to allow for innovation and experimentation in the health care marketplace and so that compliance with the physician self-referral law is not the driver of innovation or the barrier to innovation. The final exceptions at § 411.357(aa) are applicable to the compensation

arrangements between parties in a CMS-sponsored model, program, or other initiative (provided that the compensation arrangement at issue qualifies as ''value-based arrangement''), and we believe that compensation arrangements between parties in a CMS-sponsored model, program, or other initiative can be structured to satisfy the requirements of at least one of the exceptions at § 411.357(aa). It is our expectation that the suite of value-based exceptions finalized here will eliminate the need for any new waivers of section 1877 of the Act for value-based arrangements. (We note that parties are not required to utilize the value-based exceptions and may elect to use the waivers applicable to the CMS-sponsored models, programs, or initiatives in which they participate.) However, the final exceptions are not limited to CMS-sponsored models (that is, Innovation Center models) or establish separate exceptions with different criteria for arrangements that exist outside of CMS-sponsored models.

At § 411.357(aa)(1), we are finalizing an exception that applies to a value-based arrangement where a value-based enterprise has, during the entire duration of the arrangement, assumed full financial risk from a payor for patient care services for a target patient population. At § 411.357(aa)(2), we are finalizing an exception that applies to a value-based arrangement under which the physician is at meaningful downside financial risk for failure to achieve the value-based purposes of the value-based enterprise during the entire duration of the arrangement. Finally, at § 411.357(aa)(3), we are finalizing an exception that applies to any value-based arrangement, provided that the arrangement satisfies specified requirements.

We received the following general comments on the value-based exceptions and our responses follow.

Comment: Several commenters encouraged CMS and OIG to work together to more closely align their final rules. The commenters expressed concern that notable differences between the two rules, if finalized as proposed, would create a dual regulatory environment, where a value-based arrangement could meet the requirements for protection under one law but not the other, which could hinder the transition to a value-based health care delivery and payment system. These commenters expressed concern with administrative burden and compliance concerns in the event that the OIG and CMS final rules are not aligned. One commenter viewed the exceptions to the physician self-referral law as having little value if the safe harbors to the anti-kickback statute are not revised to mirror the exceptions noting that participants are likely to abide by the more stringent requirements included in the safe harbors.

Response: We share the commenters' concerns about dual regulatory schemes and the challenges for stakeholders in ensuring compliance with both. We have worked closely with OIG to ensure consistency between our respective rules to reduce administrative burden on the regulated industry. As noted in section II.A.2.a. of this final rule, the final value-based definitions at § 411.351 are aligned in nearly all respects with OIG's final value-based definitions. However, because of the fundamental differences in the statutory structure, operation, and penalties between the physician self-referral law and the anti-kickback statute, complete alignment between the exceptions to the physician self-referral law and safe harbors to the anti-kickback statute is not feasible. Reflecting these statutory differences, the regulations that CMS and OIG are finalizing include intentional differences that allow the anti-kickback statute to provide ''backstop'' protection for Federal health care programs and beneficiaries against abusive arrangements that involve the exchange of remuneration intended to induce or reward referrals under arrangements that could potentially satisfy the requirements of an exception to the physician self-referral law. In this way, the CMS and OIG regulations, operating together, balance the need for parties entering into arrangements that are subject to both laws to develop and implement value-based arrangements that avoid the strict liability referral and billing prohibitions of the physician self-referral law, while ensuring that law enforcement, including OIG, can take action against parties engaging in arrangements that are intentional kickback schemes.

Comment: A few commenters recommended that we finalize one all-inclusive exception to the physician self-referral law for any type of value-based arrangement rather than the three-exception structure proposed. These commenters asserted that replacing the three value-based exceptions with one exception would reduce the complexity of the regulatory scheme and the burden associated with the transition to value-based health care delivery and payment.

Response: We are finalizing our proposed structure with three exceptions to the physician self-referral law that apply based on the level of risk assumed by the value-based enterprise or the physician who is a party to the value-based arrangement and the characteristics of the value-based arrangement. We disagree with the commenters that one exception would be less complex and burdensome, and do not believe that a one-size fits all approach to exceptions to the physician self-referral law to facilitate the transition to a value-based health care delivery and payment system is possible.

Comment: The majority of commenters strongly urged CMS to not include in any of the final value-based exceptions the ''traditional'' requirements that compensation is set in advance, fair market value, and not determined in any manner that takes into account the volume or value of a physician's referrals or other business generated by the physician for the entity. Some commenters also requested that we not include a requirement that the value-based arrangement is commercially reasonable. The commenters opined that inclusion of these standards in the context of value-based health care delivery and payment is neither appropriate nor necessary, and asserted that inclusion of these standards would create a barrier to the transition to a value-based health care delivery and payment system, leaving the value-based exceptions of limited or no utility. These commenters noted that nonmonetary remuneration, in particular, that is provided under a value-based arrangement is not necessarily consistent with the fair market value of items or services provided by the recipient (or value-based activities undertaken by the recipient) and asserted that requiring that such compensation is fair market value would impact the ability of parties to share necessary infrastructure, care coordination, and patient engagement tools. The commenters also stated that many value-based arrangements are, by nature, related to the volume or value of referrals, and requiring that compensation is not determined in any manner that takes into account the volume or value of a physician's referrals or other business generated by the physician would limit the utility of the exceptions. Finally, a few commenters asserted that there is no need for a commercial reasonableness standard in light of the definition of ''value-based purpose,'' which the commenters interpreted to serve the same function and require the same analysis as that of the commercial reasonableness of an arrangement. These commenters also asserted that value-based arrangements are, by their

nature, commercially reasonable. In contrast, a few commenters urged CMS to include requirements that the value-based arrangement is commercially reasonable, the compensation is not determined in any manner that takes into account the volume or value of a physician's referrals or other business generated by the physician, and the compensation is fair market value in order to protect against program or patient abuse. The commenters did not explain why omitting these requirements creates a risk of program or patient abuse.

Response: As noted above and for the reasons described in the proposed rule, we are not including in the final exceptions at § 411.357(aa) the traditional requirements that compensation is set in advance, consistent with fair market value of the value-based activities provided under the value-based arrangement, and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the entity. However, we are requiring that the compensation arrangement is commercially reasonable. As we stated in the proposed rule, disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address are built into the value-based definitions and will operate in tandem with the requirements included in the exceptions to protect against program and patient abuse (84 FR 55777). It is this framework that allows us to forgo the requirements in the current exceptions to the physician self-referral law that may create significant challenges to innovation in a value-based health care delivery and payment system.

We are cognizant that requirements that remuneration be fair market value and not take into account the volume or value of a physician's referrals or the other business generated by a physician may inhibit the innovation necessary to achieve well-coordinated care that results in better health outcomes and reduced expenditures (or reduced growth in expenditures). We agree with the commenters that these standards, which play an important role in the other exceptions to the physician self-referral law, may be counter to the underlying policy goals of value-based health care delivery and payment. We also agree that compensation arrangements that qualify as value-based arrangements under the new value-based definitions at § 411.351, satisfy all the requirements of an applicable exception at final § 411.357(aa), and are aimed at reducing cost and improving quality are likely commercially reasonable. Even so, we believe that this additional program integrity safeguard is warranted. As defined at final § 411.351, ''commercially reasonable'' means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. The requirement at final § 411.357(aa)(3)(vi) will ensure that parties to a value-based arrangement structure the arrangement in a manner intended to further their legitimate business purposes, which must include achievement of the value-based purpose(s) of the value-based enterprise of which they are participants.

Comment: Several commenters urged us to create separate exceptions for CMS-sponsored model arrangements and CMS-sponsored model patient incentives consistent with existing waivers for these programs that would work in conjunction with or mirror the safe harbors at proposed 42 CFR 1001.952(ii). Some commenters expressed concern over parties having to identify and comply with an applicable exception to the physician self-referral law and also comply with the safe harbor under the anti-kickback statute for CMS-sponsored programs. Several other commenters requested assurance that all existing fraud and abuse waivers for CMS-sponsored models, programs, and initiatives will remain in effect as implemented and will not be impacted by the new exceptions for value-based arrangements.

Response: The commenters did not provide any specific examples of existing financial arrangements under a CMS-sponsored model, program, or other initiative between an entity and a physician (or immediate family member) to which none of the exceptions at final § 411.357(aa)(3) would apply. We carefully evaluated our final exceptions against the existing CMS-sponsored models, programs, and other initiatives, and are confident that at least one of the new exceptions at § 411.357(aa) is applicable to the types of compensation arrangements contemplated under each model, program, or initiative. The design of the final exceptions should result in a smooth transition from participation in a CMS-sponsored model, program, or initiative if the parties wish to continue their compensation arrangements and rely on the new value-based exceptions at § 411.357(aa). Thus, it is not necessary to establish an exception specific to arrangements undertaken pursuant to a CMS-sponsored model, program, or initiative as requested by the commenters. Importantly, the existing model-specific or program-specific fraud and abuse waivers will remain in place and are not affected by the existence of the value-based exceptions. Also, the Secretary retains authority under section 1115A(d)(1) of the Act to waive certain fraud and abuse laws as necessary solely for purposes of testing payment and service delivery models developed by the Innovation Center, and this authority can be used to address future financial arrangements under Innovation Center models that may not fit within the final value-based exceptions framework. Finally, the final fraud and abuse waivers issued in connection with the Shared Savings Program are permanent waivers that are unaffected by the value-based exceptions finalized in this final rule.

Comment: Some commenters sought clarification regarding the interaction between the value-based exceptions and existing exceptions to the physician self-referral law. A few commenters questioned whether an entity currently relies on the exception for *bona fide* employment relationships at § 411.357(c) to protect compensation arrangements with employed physicians may continue to utilize the exception at § 411.357(c), or whether its compensation arrangements that qualify as value-based arrangements must satisfy the requirements of one of the new value-based exceptions at § 411.357(aa). The commenters stated a desire to continue to utilize the exception at § 411.357(c) for value-based arrangements with employed physicians rather than the new value-based exceptions. The commenters also sought guidance regarding whether the value-based exceptions could be utilized concurrently with ''traditional exceptions'' when an entity has multiple compensation arrangements with the same physician and, if so, how requirements of the exceptions, such as the requirement that compensation is fair market value, would apply if the parties are utilizing multiple exceptions. A few commenters requested that we confirm that compensation for care coordination, quality improvement, and cost containment activities are not prohibited under the exception for *bona fide* employment relationships or the services exceptions at § 411.355.

Response: Nothing in this final rule mandates the use of the value-based exceptions. As we have stated before, parties may use any applicable exception to the physician self-referral law provided that all the requirements of the exception are satisfied (66 FR 916 and 72 FR 51047). The value-based

exceptions, however, are only available to parties that qualify under the value-based definitions. Parties may utilize the exception at § 411.357(c) to protect a value-based arrangement, however, the value-based arrangement must satisfy *all* the requirements of the exception in order to avoid the referral and billing prohibitions of the physician self-referral law. The same is true with respect to the availability of and compliance with any other existing exception that is applicable to the parties' financial relationship or the physician's referrals of designated health services. The exception for *bona fide* employment relationships includes requirements that the arrangement is commercially reasonable, the compensation paid to the physician is fair market value, and the compensation is not determined in any manner that takes into account the volume or value of the physician's referrals. None of these requirements are included in the final exceptions at § 411.357(aa). Thus, depending on the terms and conditions of the value-based arrangement, the arrangement may be unable to satisfy all the requirements of the exception for *bona fide* employment relationships. That determination is, of course, fact-specific.

Comment: Several commenters expressed concern that the requirements of the value-based definitions and exceptions could disadvantage rural providers and small physician practices that desire to participate in value-based arrangements, and that these providers and suppliers face greater challenges when transitioning to a value-based health care delivery and payment system. The commenters stated that these challenges include financial burdens, the complexity of the value-based exceptions and definitions, and inadequate resources to successfully implement value-based arrangements. Commenters urged CMS to make revisions to the proposed value-based exceptions to accommodate rural providers and small physician practices, specifically suggesting that we either limit the number of requirements under the value-based exceptions that would be applicable to rural providers and small physician practices to help alleviate the burden associated with complying with the exceptions or establish a separate, less onerous exception applicable only to these providers and suppliers.

Response: We are not persuaded that an exception for value-based arrangements that is exclusively available to rural providers and small physician practices is necessary, nor are we revising the exceptions to limit the requirements under the value-based exceptions applicable to these providers and suppliers. We understand the challenges faced by rural providers and small physician practices, including resource limitations, and appreciate the important role of rural providers as a safety net for their communities. The value-based arrangements exception finalized at § 411.357(aa)(3) is applicable to all value-based arrangements, regardless of the size or nature of the parties to the arrangement, the financial risk undertaken by the value-based enterprise, or the financial risk undertaken by the physician who is a party to the value-based arrangement. We expect that this exception may be utilized by rural providers and small physician practices more frequently than the full financial risk and meaningful downside financial risk exceptions. As discussed elsewhere in this final rule, we are not requiring a financial contribution from the recipient of remuneration under any of our final value-based exceptions. We believe this addresses some of the commenters' concerns.

(1) Full Financial Risk (§ 411.357(aa)(1))

We proposed at § 411.357(aa)(1) an exception to the physician self-referral law (the ''full financial risk exception'') that applies to value-based arrangements between VBE participants in a value-based enterprise that has assumed ''full financial risk'' for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time; that is, the value-based enterprise is financially responsible (or is contractually obligated to be financially responsible within the 6 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of such patient care items and services. For Medicare beneficiaries, we noted that we intend for this requirement to mean that the value-based enterprise, at a minimum, is responsible for all items and services covered under Parts A and B. We are finalizing the exception with one modification. We are extending the period of time during which the exception will be available prior to the value-based enterprise's financial responsibility for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population. Specifically, we are replacing the requirement that the value-based enterprise is contractually obligated to be financially responsible within the 6 months following the commencement date of the value-based arrangement with a 12-month timeframe. Thus, under this final rule, the value-based enterprise must be financially responsible (or must be contractually obligated to be financially responsible within the 12 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. As described in more detail below, we believe that extending this ''pre-risk period'' to 12 months is consistent with the timeframe established in the Shared Savings Program pre-participation waiver (80 FR 66742), and, as with the Shared Savings Program pre-participation waiver, we do not believe that establishing a 12-month pre-risk period poses a risk of program or patient abuse.

As we stated in the proposed rule, full financial risk may take the form of capitation payments (that is, a predetermined payment per patient per month or other period of time) or global budget payment from a payor that compensates the value-based enterprise for providing all patient care items and services for a target patient population for a predetermined period of time (84 FR 55779). We noted that the full financial risk exception would not prohibit other approaches to full financial risk and sought comment on other approaches to full financial risk that may exist currently or that stakeholders anticipate for the future. We are not prescribing a specific manner for the assumption of full financial risk in this final rule.

A value-based enterprise need not be a separate legal entity with the power to contract on its own (84 FR 55779). Rather, networks of physicians, entities furnishing designated health services, and other components of the health care system collaborating to achieve the goals of a value-based health care system, organized with legal formality or not, may qualify as a value-based enterprise. A value-based enterprise may assume legal obligations in different ways. For example, all VBE participants in a value-based enterprise could each sign the contract for the value-based enterprise to assume full financial risk from a payor. Or, the VBE participants in a value-based enterprise could have contractual arrangements among themselves that assign risk jointly and severally. Or, similar to physicians in an independent practice association (IPA), VBE participants could vest the authority to bind all VBE participants in the value-based enterprise with a designated person that

contracts for the assumption of full financial risk on behalf of the value-based enterprise and its VBE participants. As explained in more detail below, we are not requiring that the value-based enterprise is a separate legal entity with contracting powers or requiring a particular structure for the value-based enterprise.

The value-based enterprise's financial risk must be prospective; that is, the contract between the value-based enterprise and the payor may not allow for any additional payment to compensate for costs incurred by the value-based enterprise in providing *specific* patient care items and services to the target patient population, nor may any VBE participant claim payment from the payor for such items or services. We define ''prospective basis'' in this final rule at § 411.357(aa)(1)(vii) to mean that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population. As noted in the proposed rule (84 FR 55780) and discussed more fully below, the final definition of ''full financial risk'' does not prohibit a payor from making payments to a value-based enterprise to offset losses incurred by the enterprise above those prospectively agreed to by the parties. The payment of shared savings or other incentive payments for achieving quality, performance, or other benchmarks are also not prohibited. The final exception is available to protect value-based arrangements entered into in preparation for the implementation of the value-based enterprise's full financial risk payor contract where such arrangements begin after the value-based enterprise is contractually obligated to assume full financial risk for the cost of patient care items and services for the target patient population but prior to the date the provision of patient care items and services under the contract begin. As stated above, the final exception limits this period to the 12 months prior to the effective date of the full financial risk payor contract. In other words, the value-based enterprise must be at full financial risk within the 12 months following the commencement of the value-based arrangement.

We believe that full financial risk is one of the defining characteristic of a mature value-based payment system. When a value-based enterprise is at full financial risk for the cost of all patient care services, the incentives to order unnecessary services or steer patients to higher-cost sites of service are diminished. Even when downstream contractors are paid on something other than a full-risk basis, the value-based enterprise itself is incented to monitor for appropriate utilization, referral patterns, and quality performance, which we believe helps to reduce the risk of program or patient abuse. Accordingly, these kinds of payment limitations provide stronger and more effective safeguards against increases in the volume and costs of services than the physician self-referral law ever placed on the FFS system. Nonetheless, as a precaution, we proposed and are finalizing several important safeguards in the full financial risk exception.

The value-based enterprise must be at full financial risk during the *entire duration* of the value-based arrangement for which the parties to the arrangement seek protection (84 FR 55780). Thus, the final exception will not protect arrangements that begin at some point during a period when the value-based enterprise has assumed full financial risk, but that continue into a timeframe when the safeguards intrinsic to full-financial risk payment, such as the disincentive to overutilize or stint on medically necessary care, no longer exist. However, one or both of the other exceptions finalized at § 411.357(aa)(2) and (3) may be available to protect value-based arrangements that exist during a period when the value-based enterprise is not at full financial risk (or contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population.

We also proposed and are finalizing a requirement that the remuneration under the value-based arrangement is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. As we discussed in the proposed rule, we recognize that payments under certain incentive payment arrangements, such as gainsharing arrangements, may be difficult to tie to specific items or services furnished by a VBE participant (84 FR 55780). We do not interpret the requirement at § 411.357(aa)(1)(ii) as mandating a one-to-one payment for an item or service (or other value-based activity). Gainsharing payments, shared savings distributions, and similar payments may result from value-based activities undertaken by the recipient of the payment for patients in the target patient population. The requirement that the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population addresses this issue. We intend for this to be an objective standard; that is, the remuneration must, in fact, be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population (84 FR 55780). The final exception, therefore, will not protect payments for referrals or any other actions or business unrelated to the target patient population, such as general marketing or sales arrangements. With respect to in-kind remuneration, it is our position that the remuneration must be necessary and not simply duplicate technology or other infrastructure that the recipient already has. Finally, although the remuneration must be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, parties would not be prohibited from using the remuneration for the benefit of patients who are not part of the target patient population.

In the proposed rule, we discussed the fact that integrated into most of the CMS-sponsored models is a requirement that any remuneration between parties to an allowable financial arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient in the assigned patient population (84 FR 55780). This is an important safeguard for patient safety and quality of care, regardless of whether Medicare is the ultimate payor for the services. Therefore, we proposed a requirement at § 411.357(aa)(1)(iii) that remuneration under a value-based arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not. We are finalizing this requirement at § 411.357(aa)(1)(iii). We note that remuneration that leads to a reduction in medically necessary services would be inherently suspect and could implicate sections 1128A(b)(1) and (2) of the Act.

In addition, we proposed to protect only those value-based arrangements under which remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement (84 FR 55781). Although this requirement is similar to the requirement that remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, as discussed in the proposed rule, it is

intended to address a different concern. We are finalizing at § 411.357(aa)(1)(iv) the requirement that the remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement. The final exception does not protect arrangements where one or both parties have made referrals or other business not covered by the value-based arrangement a condition of the remuneration. By way of example, if the value-based enterprise is at full financial risk for the total cost of care for all of a commercial payor's enrollees in a particular county, the exception will not protect a value-based arrangement between an entity and a physician that are VBE participants in the value-based enterprise if the entity requires the physician to refer Medicare patients who are not part of the target patient population for designated health services furnished by the entity. Similarly, the exception will not protect a value-based arrangement related to knee replacement services furnished to Medicare beneficiaries if the arrangement requires that the physician perform all his or her other orthopedic surgeries at the hospital.

We also proposed and are finalizing a requirement at § 411.357(aa)(1)(v) related to directing a physician's referrals to a particular provider, practitioner, or supplier (84 FR 55781). Under final § 411.357(aa)(1)(v), if remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions: (A) The requirement to make referrals to a particular provider, practitioner, or supplier must be set out in writing and signed by the parties; and (B) the requirement to make referrals to a particular provider, practitioner, or supplier may not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. See section II.B.4. of this final rule for a complete discussion of our interpretation of this requirement.

Finally, we proposed to require that records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement be maintained for a period of at least 6 years and made available to the Secretary upon request (84 FR 55781). We noted in the proposed rule that requirements similar to this are found in our existing regulations in the group practice rules at § 411.352(d)(2) and (i), the exception for physician recruitment at § 411.357(e)(4)(iv), and the exception for assistance to compensate a nonphysician practitioner at § 411.357(x)(2) (84 FR 55781). We are finalizing at § 411.357(aa)(3)(xi) the requirement that records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request. We expect that parties are familiar with these requirements and that the maintenance of such records is part of their routine business practices.

As we discussed in the proposed rule (84 FR 55781), we consider the exception at § 411.357(aa)(1) comparable, in some respects, to the exception at § 411.357(n) for risk-sharing arrangements, which, as we noted in Phase II, is intended to be a broad exception with maximum flexibility, covering all risk-sharing compensation paid to a physician by any type of health plan, insurance company, or health maintenance organization (that is, any ''managed care organization'' (MCO)) or IPA, provided the arrangement relates to enrollees and meets the conditions set forth in the exception (69 FR 16114). A downstream arrangement that creates an indirect compensation arrangement between an MCO or IPA and a physician is included within the scope of the exception for risk-sharing arrangements. (See section II.A.2.b.(4) of this final rule for a full discussion of the applicability or the exception for risk-sharing arrangements at § 411.357(n).) Although the final exception at § 411.357(aa)(1) is not limited to ''risk-sharing compensation'' paid to a physician, but, rather, covers any type of remuneration paid under a value-based arrangement that is for or results from value-based activities undertaken by the recipient of the remuneration, for the reasons discussed throughout section II.A. of this final rule, we believe that the flexibility provided in the exception for risk-sharing arrangements is also warranted in the full financial risk exception. Finally, like the exception at § 411.357(n) for risk-sharing arrangements, we did not propose, nor are we finalizing, documentation requirements in the full financial risk exception. Nevertheless, it is a good business practice to reduce to writing any arrangement between referral sources as it allows the parties to monitor and confirm that an arrangement is operating as intended.

We received the following comments and our responses follow.

Comment: Several commenters urged CMS to expand the definition of ''full financial risk'' at § 411.357(aa)(1)(vii) to exclude defined sets of patient care items or services for a target patient population, or specific diseases or conditions, similar to episode-based bundled payment models. By way of example, commenters suggested that full financial risk should be limited to only the items and services required to treat patients with diabetes or during an episode of care for a knee replacement. Commenters perceived the full financial risk exception as having limited utility, asserting that the health care industry is currently not well-positioned to take on full financial risk for all patient care items and services covered by the applicable payor for each patient in the target patient population. Commenters suggested that allowing protection under the full financial risk exception for arrangements where the parties take on full financial risk for only a subset of items or services covered by the applicable payor, such as joint replacement surgery, would increase the utility of the full financial exception and help to facilitate the transition to a value-based health care delivery and payment system.

Response: We are not revising the definition of ''full financial risk'' to mean a defined set of patient care items or services (similar to episode-based bundled payment models) or anything less than financial responsibility, on a prospective basis, for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population. To do so could undermine the Secretary's policy goals of moving more health care providers and practitioners into two-sided risk payment structures. The full financial risk exception applies to value-based arrangements between VBE participants in a value-based enterprise that has assumed ''full financial risk'' on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. It also applies to a value-based arrangement between the value-based enterprise (if it is an entity as defined at § 411.351) and a physician who is a VBE participant in the value-based enterprise. The value-based enterprise must be financially responsible (or be contractually obligated to be financially responsible within the 12 months following the commencement date of the value-based

arrangement) on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. As noted in the proposed rule and above, we believe that full financial risk is an important defining characteristic of a mature value-based health care delivery and payment system (84 FR 55780). When a value-based enterprise is at full financial risk for the cost of all patient care items and services, the incentives to order unnecessary services or steer patients to high-cost sites of services are diminished. Those same incentives are not necessarily present in episode-based bundled payment models. Expanding the applicability of the exception at § 411.357(aa)(1) to protect value-based arrangements under episode-based bundled payment models would result in heightened program integrity concerns, and therefore, would not fall within the Secretary's authority under section 1877(b)(4) of the Act upon which we relied to establish this exception. We recognize that providers may not be well-positioned at this time to transition to a full financial risk model; however, it is our hope that, by reducing the burden of the physician self-referral law, we can provide a pathway for participants in the value-based system to evolve and more meaningfully participate in the value-based system. As discussed in detail in II.A.2.b.(3). of this final rule, we are finalizing at § 411.357(aa)(3) an exception applicable to value-based arrangements where the value-based enterprise assumes less than full financial risk, including arrangements where neither the value-based enterprise nor the parties to the particular arrangement have assumed any financial risk. That exception may facilitate the entry of providers and suppliers into value-based health care delivery and payment with the goal of moving eventually to two-sided risk models.

Comment: Several commenters stated that the full financial risk exception would be of limited utility if high-cost or specialty items and services, such as organ transplants or pharmacy benefits, are not carved out of the definition of ''full financial risk.'' The commenters noted that, even in more advanced value-based arrangements, payors exclude high-cost or specialty items or services from the risk arrangement. The commenters urged CMS to permit a value-based enterprise to qualify as being at full financial risk without taking on the responsibility for high cost or specialty items and services. Similarly, these commenters requested clarification regarding the ability of the value-based enterprise to offset losses while still meeting the definition of full financial risk for purposes of the exception. Other commenters urged CMS to allow a value-based enterprise to enter into payor arrangements with risk mitigation terms to protect against catastrophic losses, such as risk corridors, global risk adjustments, reinsurance, stop loss agreements.

Response: We decline to carve out high-cost or specialty items or services from the definition of ''full financial risk.'' In addition, we do not believe that revisions are necessary to specifically address mechanisms by which parties to a full financial risk payor arrangement may protect against significant or catastrophic losses. Further, the exclusion of high-cost or specialty items and services could potentially interfere with private payor contracts among health care providers, suppliers, and physicians. Importantly, nothing in the final full financial risk exception or the definition of ''full financial risk'' prohibits a value-based enterprise from contracting with a payor for stop-loss protection or applying risk corridors to limit exposure to significant losses related to such high-cost items or services or overall expenses. A payor arrangement may include risk mitigation terms such as risk corridors, global risk adjustments, reinsurance, or stop-loss provisions to protect against significant and catastrophic losses. As noted above, the financial risk assumed by the value-based enterprise must be prospective; thus, the contract between the value-based enterprise and the payor may not allow for any additional fee for service or other payments to compensate for costs incurred by the value-based enterprise in providing specific patient care items and services to the target patient population, nor may any VBE participant claim payment from the payor for such items or services.

Risk mitigation tools are not new to CMS-sponsored value-based initiatives. In fact, some of the initiatives of the Innovation Center, where Medicare is the payor, anticipate potential burdens on participants related to high cost items and services and the need for protection against significant and catastrophic losses. These Innovation Center initiatives include stop-loss provisions to mitigate the risk of overall costs being higher than expected. For instance, the Bundled Payment for Care Improvement, Next Gen ACO, and Comprehensive Care for Joint Replacement models all include some form of stop-loss assurance to mitigate financial risk.

Finally, there is nothing in this final rule that will prohibit a value-based enterprise and a payor from negotiating and designing a full financial risk payor arrangement that would address the concerns raised by the commenters. We are not imposing a specific limit on the amount of loss coverage a value-based enterprise may have, but we caution that we will expect any stop-loss or other risk adjustment provisions to act as protection for the value-based enterprise against catastrophic losses and not a means by which to shift material financial risk back to the payor. To be clear, the definition of ''full financial risk'' would not permit the full offset of a value-based enterprise's losses.

Comment: The majority of commenters agreed that the full financial risk exception should extend to compensation arrangements related to activities taken in preparation for the implementation of the value-based enterprises' full financial risk payor contract, but requested that CMS extend the 6-month ''pre-risk'' period to a 12-month period. The commenters noted that at least 12 months of preparation are often necessary to develop and operationalize a successful value-based enterprise, even when it will not be assuming full financial risk. Commenters highlighted activities such as the development of care redesign protocols, implementation of IT infrastructure, and deployment of care coordinators as necessary for the successful undertaking of full financial risk by a value-based enterprise and its VBE participants.

Response: We are persuaded to extend the ''pre-risk'' period under the full financial risk exception to 12 months. Under the regulation finalized in this final rule, the value-based enterprise must be financially responsible (or be contractually obligated to be financially responsible within the 12 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. Extending this pre-risk period to 12 months should allow parties sufficient time to work together in preparation for taking on full financial risk. A 12-month period is consistent with the Shared Savings Program pre-participation waiver, and we are not aware of any program integrity concerns with respect to the 12-month start-up period to date. We see no reason why providing for a 12-

month pre-risk period in the full financial risk exception would pose a risk of program or patient abuse.

Comment: Some commenters explained that certain States, such as California, require providers or suppliers that assume full financial risk for health care items and services are required to become licensed as a health plan. The commenters noted that the expense and regulatory burden associated with becoming a licensed health plan would deter most providers or suppliers from taking that step, making the full financial risk exception of no utility to them. The commenters recommended that CMS modify the full financial risk exception to address this State law issue. Some of the commenters also noted that certain States prohibit a provider or supplier from assuming financial risk for items and services other than those typically provided by that provider or supplier type. For instance, a hospital could not assume financial risk for physician services and vice versa.

Response: We are not prescribing a specific manner for the assumption of full financial risk by a value-based enterprise. The full financial risk exception applies to value-based arrangements between VBE participants in a value-based enterprise that has assumed full financial risk on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. Nothing in this final rule precludes the various VBE participants in the value-based enterprise from aggregating the risk that each individual VBE participant assumes to reach full financial risk for the value-based enterprise as a whole. For instance, assume a value-based enterprise has as its VBE participants a hospital, skilled nursing facility, physicians, and a full complement of providers and suppliers that, together, provide all the patient care services covered by an applicable payor. If each of the VBE participants is at full financial risk for the cost of all patient care items or services that it furnishes, the VBE participants could aggregate their risk so that the value-based enterprise is, in total, at full financial risk for the cost of all patient care items or services covered by the applicable payor. Essentially, the hospital could assume full financial risk for hospital services, the skilled nursing facility could assume full financial risk for skilled nursing services, the physicians could assume full financial risk for physician services, etc. As long as there are no services covered by the applicable payor for which the VBE participants have not assumed full financial risk, the value-based enterprise will be at full financial risk for purposes of § 411.357(aa)(1). We see no reason why allocating the full financial risk among the VBE participants of the value-based enterprise—as opposed to a single organization (the value-based enterprise) assuming the full financial risk—would pose an additional risk of program or patient abuse. Finally, we note that nothing in this final rule preempts any applicable State law, and we remind parties that other exceptions may be available to protect arrangements where State law restrictions make satisfaction of certain requirements of an exception challenging or impossible.

Comment: Many commenters acknowledged the importance of preserving patient choice but stressed that, in a value-based health care delivery and payment system, the ability to guide a patient to a high quality provider is imperative. The commenters requested that we include any patient choice requirements in the regulation text of the value-based exceptions rather than cross-referencing the requirements of the special rules on compensation at § 411.354(d)(4)(iv).

Response: As discussed above, protection of patient choice is especially critical in the context of referrals made by a physician to an entity with which the physician has a financial relationship, as the physician's financial self-interest may impact, if not infringe on, a patient's right to control who furnishes his or her care. We are finalizing in the full financial risk exception a separate requirement to ensure that, regardless of the nature of the value-based arrangement and the value-based enterprise's value-based purpose(s), the regulation adequately protects a patient's choice of health care provider, the physician's medical judgment, and the ability of health insurers to efficiently provide care to their members. The final exception provides at § 411.357(aa)(1)(v) that, if remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions: (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties; and (B) the requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. We have included this language in all three of the value-based exceptions.

Comment: A few commenters questioned whether the full financial risk exception is even necessary, suggesting that CMS should instead modify the exception at § 411.357(n) for risk-sharing arrangements to accommodate value-based arrangements where the value-based enterprise is at full financial risk.

Response: We decline to modify the exception at § 411.357(n) to accommodate value-based arrangements as requested by the commenters. As discussed more fully in section II.A.2.b.(4) of this final rule, the exception at § 411.357(n) applies to compensation arrangements between an MCO or an IPA and a physician for services provided to enrollees of a health plan, provided that the compensation arrangement qualifies as a risk-sharing arrangement. The compensation arrangement between the MCO or IPA and the physician may be direct or indirect. The exception does not apply to a compensation arrangement—whether direct or indirect—between a physician and an entity that is anything other than an MCO or IPA. The value-based exceptions finalized in this final rule will apply to any value-based arrangement, direct or indirect, between a physician and *any entity* that furnishes designated health services to which the physician makes referrals. Thus, the value-based exceptions are broader in applicability than the exception for risk-sharing arrangements. As discussed in the proposed rule and above, we have designed a carefully woven fabric of definitions and exceptions that protect against program and patient abuse while providing flexibility for experimentation in the design and implementation of value-based care arrangements (84 FR 55777). We believe that this framework is crucial to achieving the Department's goal of moving to a value-based health care delivery and payment system, and that most value-based arrangements between an entity and a physician in a value-based enterprise that has assumed full financial risk should remain within this framework.

(2) Value-Based Arrangements With Meaningful Downside Financial Risk to the Physician (§ 411.357(aa)(2))

As we stated in the proposed rule, a few CMS RFI commenters opined that the health care industry is in the early

stages of its transition to value-based health care delivery and payment (84 FR 55781). After reviewing the comments on the CMS RFI and the proposed rule, we acknowledge that, although CMS, non-Federal payors, and a significant segment of the health care industry have made advancements in value-based health care delivery and payment, many physicians and providers are not yet prepared or willing to be responsible for the total cost of patient care services for a target patient population. However, we are also aware that some physicians are participating in or considering participating in alternative payment models that provide for potential financial gain in exchange for the undertaking of some level of downside financial risk.

Financial risk assumed directly by a physician will likely affect his or her practice and referral patterns in a way that curbs the influence of traditional FFS, volume-based payment. Further, financial risk is tied to the achievement or, or failure to achieve, value-based purposes incents the type of behavior-shaping necessary to transform our health care delivery system into one that improves patient outcomes, eliminates waste and inefficiencies, and reduces the costs to or growth in expenditures of payors. Arrangements under which a physician is at meaningful downside financial risk for failure to achieve predetermined cost, quality, or other performance benchmarks contain inherent protections against program or patient abuse. In recognition of this, we proposed an exception that would protect remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise (the ''meaningful downside financial risk exception'') (84 FR 55781). Under the meaningful downside financial risk exception, although the physician must be at meaningful downside financial risk for the entire term of the value-based arrangement, the remuneration could be paid to or from the physician.

We proposed to define ''meaningful downside financial risk'' to mean that the physician is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement. We stated that we believe that this level of financial risk is high enough to curb the influence of traditional FFS, volume-based payment and achieve the type of behavior-shaping necessary to facilitate achievement of the goals set forth in this final rule (84 FR 55782). We related the definition of ''meaningful downside financial risk'' to the 25 percent threshold determined by the Secretary for the statutory and regulatory exceptions for physician incentive plans at section 1877(e)(3)(B) of the Act and § 411.357(d)(2), respectively, which reference ''substantial financial risk'' to a physician (or physician group), and sought comment on whether defining meaningful downside financial risk as 25 percent of the value of the remuneration the physician receives under the value-based arrangement is appropriate. Upon consideration of the public comments, we are revising the definition of ''meaningful downside financial risk'' to mean that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement. Because the exception does not limit the type of remuneration that may be provided, under the final regulation, the risk of repayment or the amount the physician must be at risk to forgo may be no less than 10 percent of the *value* of the remuneration to account for remuneration that may be provided in-kind, such as infrastructure or care coordination services. In the proposed rule, we also provided an alternative definition to meaningful downside financial risk that would also include the physician's full financial risk to the entity, recognizing that a physician who assumes full financial risk for all or a defined set of patient care services for the target patient population would certainly be considered at ''meaningful downside financial risk'' (84 FR 55782). We are not finalizing our proposal for an expanded definition of ''meaningful downside financial risk.''

As discussed in the proposed rule, because the exception at § 411.357(aa)(2) does not require the type of global risk to the value-based enterprise that is required in the full financial risk exception, additional or different requirements are necessary to protect against program or patient abuse (84 FR 55782). We proposed requiring that the physician must be at meaningful downside financial risk for the entire duration of the value-based arrangement to curtail any gaming that could occur by adding meaningful downside financial risk to a physician during only a short portion of an arrangement. We are finalizing this requirement at § 411.357(aa)(2)(i). To buttress our oversight ability and that of our law enforcement partners, we proposed a requirement that the nature and extent of the physician's financial risk is set forth in writing. We are finalizing this requirement at § 411.357(aa)(2)(ii). We note that this is also a good business practice that allows the parties to monitor their value-based arrangements and ensure that they are operating as intended. For similar reasons, but also as a safeguard against manipulating a value-based arrangement to reward referrals, we proposed to require that the methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided. We noted that the special rule on compensation at § 411.354(d)(1) that deems compensation to be set in advance when certain conditions are met would apply, however, that provision is merely a deeming provision and parties are free to confirm satisfaction of the requirement another way. We are finalizing this requirement at § 411.357(aa)(2)(iii).

Integrated into most of the CMS-sponsored models is a requirement that any remuneration between parties to an allowable financial arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient in the assigned patient population (84 FR 55782). This is an important safeguard for patient safety and quality of care, regardless of whether Medicare is the ultimate payor for the services, and we proposed including this safeguard in the meaningful downside financial risk exception by requiring that remuneration is not provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not. Remuneration that leads to a reduction in medically necessary services would be inherently suspect and could implicate sections 1128A(b)(1) and (2) of the Act. We are finalizing this requirement at § 411.357(aa)(2)(v).

For the reasons we explained with respect to the full financial risk exception, we proposed to include in the meaningful downside financial risk exception requirements that the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population; remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement; and that records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the

Secretary upon request. We are finalizing our proposals to include these requirements in the meaningful downside financial risk exception at § 411.357(aa)(2)(iv), (vi), and (viii).

We also proposed a requirement at § 411.357(aa)(2)(vii) related to directing a physician's referrals to a particular provider, practitioner, or supplier (84 FR 55781). Under final § 411.357(aa)(2)(vii), if remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions: (1) The requirement to make referrals to a particular provider, practitioner, or supplier must be set out in writing and signed by the parties; and (2) the requirement to make referrals to a particular provider, practitioner, or supplier may not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. See section II.B.4. of this final rule for a complete discussion of our interpretation of this requirement.

We received the following comments on the proposed meaningful downside financial risk exception. Our responses follow.

Comment: Several commenters disagreed with the design of the meaningful downside financial risk exception and the focus of the exception on the physician's level of risk rather than that of the entity. The commenters viewed the meaningful downside financial risk exception, as proposed, as being of limited utility and not reflective of current real-world financial risk arrangements. Some commenters urged CMS to modify the meaningful downside financial risk exception to protect arrangements where the entity assumes the financial risk noting that entities, such as hospitals, are better positioned to assume risk from payors. These commenters expressed concern as to whether physician behavior has evolved to the point of being able to assume meaningful downside financial risk as required by the exception. Some commenters requested that we permit an entity to assume meaningful downside financial risk and then allocate the risk down to the physician.

Response: We are not making the modifications suggested by the commenters. These commenters appear to misunderstand the scope of the meaningful downside financial risk exception and the intent behind it. The meaningful downside financial risk exception covers individual compensation arrangements that qualify as value-based arrangements between an entity and a physician that are VBE participants in the same value-based enterprise, regardless of whether the value-based enterprise or the entity has assumed financial risk from a payor. The exception is available to protect value-based arrangements under which the physician has assumed financial risk *from the entity* that is party to the arrangement, and where such risk is tied to the achievement of the value-based purpose(s) of the value-based enterprise of which the physician and the entity are VBE participants. The value-based exceptions at § 411.357(aa) are designed to accommodate movement toward two-sided financial risk. Although we recognize that many physicians may not be prepared or willing to assume full (or substantially full) financial risk, the exception at § 411.357(aa)(2) is available to protect those value-based arrangements under which either meaningful downside financial risk is incorporated into the physician's compensation. There is great potential for behavior-shaping when a physician's failure to achieve value-based purposes is tied to his or her remuneration. This behavior-shaping is critical to transforming our health care delivery system into one that improves patient outcomes, eliminates waste and inefficiencies, and reduces costs to or growth in expenditures of payors.

Comment: Most of the commenters that addressed the proposed exception at § 411.357(aa)(2), disliked the 25 percent threshold for qualification as meaningful downside financial risk. These commenters asserted that a 25 percent threshold is too high and would limit physician participation in value-based health care delivery and payment systems. Some of the commenters suggested that physicians who are new to value-based health care would be reluctant to put 25 percent of their compensation at risk. These commenters requested that we reduce the threshold to 10 percent, referencing a 2018 Deloitte Survey of U.S. physicians [5] that surveyed 624 primary care and specialty physicians practicing in a variety of health care settings and found that most physicians are willing to tie approximately 10 percent of their compensation to quality and cost measures (the Deloitte Study). Several other commenters suggested a 5 percent threshold, noting that certain CMS payment systems or programs, such as advanced APMs and MIPS APMs, set financial risk percentages for physicians ranging from 5 to 9 percent. A few commenters suggested that we adopt a threshold of 15 percent for consistency with the contribution requirement under the exception for EHR items and services at § 411.357(w). Some of the commenters suggested a scaled approach under which the exception initially would require a lower level of downside financial risk and increase to a higher level of downside financial risk as the physician acclimates to and participates in the value-based health care delivery and payment system. The commenters suggested that, in the alternative, CMS could set a lower threshold for meaningful downside financial risk in this final rule and increase the threshold in a future rulemaking. A few commenters viewed the 25 percent threshold as appropriate and consistent with the physician incentive plan rules applicable to Medicare and Medicaid managed care plans and federal health maintenance organizations.

Response: We find the commenters' statements and the Deloitte Study compelling, and our final regulation incorporates a lower threshold for meaningful downside financial risk of no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement. The Deloitte Study found that physicians are willing to tie a greater percentage of their compensation (10 percent) to cost and quality measures than they have been previously, but physicians still need cost and quality data and analytic tools that may not be readily available to all physicians to find success in a value-based health care delivery and payment system. We believe that the assumption by a physician of 10 percent downside financial risk is sufficient to curb the influences of traditional FFS payment systems. We reiterate that, the downside financial risk threshold, for purposes of the exception at § 411.357(aa)(2), relates to remuneration *from an entity* to a physician. Therefore, we do not believe that it is appropriate to link this threshold to the level of risk related to payments for services *from a payor,* for example, by linking to risk levels under MIPS or the Medicare Access and CHIP Reauthorization Act (MACRA).

Comment: Several commenters urged us to revise the definition of ''meaningful downside financial risk'' to mirror the risk levels found in OIG's proposed safe harbor for value-based arrangements with substantial downside financial risk. The commenters suggested this would avoid the need for

[5] *https://www2.deloitte.com/us/en/insights/industry/health-care/volume-to-value-based-care.html (last accessed June 18, 2020).*

parties to navigate different regulatory frameworks under the anti-kickback statute and physician self-referral law. These commenters asserted that the lack of alignment between OIG and CMS could create unnecessary burden on the regulated industry.

Response: It appears that the comments are based on a perception of the meaningful downside financial risk exception as a parallel to the OIG substantial downside financial risk safe harbor. It is not. Under the substantial downside financial risk safe harbor, the required financial risk is at the value-based enterprise level. That is, the value-based enterprise, either directly or through its VBE participants, must assume substantial downside financial risk in order for the safe harbor to be available. Under the meaningful downside financial risk exception, the focus is on the risk assumed by the individual physician to the value-based arrangement being assessed for satisfaction of the requirements of the exception. It would be incongruous to match the risk requirements in the exception and safe harbor as requested by the commenters.

Comment: Some commenters questioned whether the meaningful downside financial risk exception applies only when a physician is required to repay remuneration already received or whether the exception would also apply to value-based arrangements under which a portion of the physician's compensation is withheld until achievement of the value-based purpose(s) of the value-based enterprise. Other commenters asked whether the meaningful downside financial risk exception is applicable to value-based arrangements under which the physician is eligible to receive or would forgo incentive pay, depending on whether the physician satisfies the goals of the value-based arrangement or the performance or quality standards required under the value-based arrangement. A few commenters expressed concern that a repayment requirement could result in noncompliance where cash flow or other factors impact the ability of the physician to make repayment. The commenters also asserted that a ''repayment-only'' policy is inconsistent with the structure of many financial risk arrangements that permit payments to either be withheld, reduced, or repaid for not meeting stated goals or performance and quality standards.

Response: We are clarifying the regulation at § 411.357(aa)(2)(ix) to explicitly state that meaningful downside financial risk means that the physician is responsible to repay *or forgo* no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement. The scope of the meaningful downside financial risk exception is not limited to value-based arrangements under which a physician is required to repay remuneration already received from the entity. The structures of the financial terms of a value-based arrangement described by the commenters are permissible, provided that the arrangement otherwise complies with the value-based definitions and satisfies all the requirements of the meaningful downside financial risk exception. Withholds, repayment requirements, or incentive pay tied to meeting goals or outcome measures are all permissible options for structuring the financial terms of a value-based arrangement between an entity and a physician, provided that the physician's downside financial risk is tied to the achievement of the value-based purpose(s) of the value-based enterprise and not the goals of the parties or the arrangement (unless the parties alone comprise the value-based enterprise). In addition, the meaningful downside financial risk exception applies only where the physician is at risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement. To illustrate, if a physician is entitled to a base payment of $50,000 with the ability to earn an additional $25,000 for performing certain value-based activities, meaningful downside financial risk equals at least 10 percent of the total compensation of $75,000, or $7,500. The $25,000 that is at risk for purposes of this example exceeds the 10 percent requirement. However, unless the receipt of the $25,000 is tied to the achievement of the value-based purpose(s) of the value-based enterprise, the arrangement will not satisfy the requirement at final § 411.357(aa)(2)(i). By way of another example, assume that there exists a value-based arrangement between an entity and a physician that are the only VBE participants in the value-based enterprise (that is, they are a value-based enterprise of two) under which the total remuneration potentially due to the physician is $100,000, but $20,000 is withheld and payable only upon successfully completing the value-based activities called for under the arrangement. Meaningful downside financial risk equals at least 10 percent of the total compensation of the $100,000 total available remuneration, or $10,000. The $20,000 withhold in this example exceeds the 10 percent requirement.

Comment: Some commenters shared their confusion regarding the proposed alternative definition of meaningful downside financial risk under which a physician would be considered to be at meaningful downside financial risk if the physician is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. The commenters requested that CMS revise or omit the alternative definition. The commenters also questioned the utility of the definition, noting that it is unlikely that an individual physician would assume full financial risk from an entity (or a payor).

Response: We agree with the commenters that it is unlikely that an individual physician would assume full financial risk from the entity with which the physician has the value-based arrangement for the cost of all or a defined set of items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. We are not finalizing this portion of the definition of ''meaningful downside financial risk'' and have omitted the language from the final regulation. As set forth at final § 411.357(aa)(2)(ix), meaningful downside financial risk means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

Comment: A number of commenters requested that CMS adopt the same ''pre-risk'' period during which the exception is applicable prior to the assumption of financial risk that was included in the proposed full financial risk exception, but did not explain the need for a pre-risk period under the meaningful downside financial risk exception, which applies only to a single arrangement between an entity and a physician. Most of the commenters requested a 12-month ''pre-risk'' period.

Response: We are not permitting the use of the meaningful downside financial risk exception during the period prior to the physician's assumption of meaningful downside financial risk. We see no need to allow the use of the exception at § 411.357(aa)(2) prior to the physician's assumption of meaningful downside financial risk and believe that it would be a program integrity risk to do so. The Secretary's authority at section

1877(b)(4) of the Act to issue exceptions to the physician self-referral law is limited to only those financial relationships that the Secretary determines do not pose a risk of program or patient abuse. We are concerned that unscrupulous parties could ''front load'' the remuneration by providing high-value remuneration to the physician in the ''pre-risk'' period before the physician is required to assume meaningful downside financial risk. This concern is heightened in light of the final definition of ''meaningful downside financial risk,'' which sets the threshold for downside financial risk at 10 percent of the value of the remuneration rather than the 25 percent threshold proposed. Further, we note that financial risk in an arrangement between an entity and an individual physician, which is the foundation of the meaningful downside financial risk exception, is not an analog to the financial risk assumed by a value-based enterprise, which is the foundation of the full financial risk exception. As we explained in section II.A.2.b.(1). of this final rule, VBE participants may need to develop infrastructure and perform certain activities necessary to be successful in a full financial risk payment model before the enterprise's assumption of full financial risk. The same is not true with respect to a physician who assumes meaningful downside financial risk under an individual value-based arrangement with an entity.

Comment: Several commenters asserted that the requirement that the methodology used to determine the amount of the remuneration under the value-based arrangement is set in advance of the undertaking of the value-based activities for which the remuneration is paid fails to provide sufficient flexibility. The commenters requested that we ''soften'' the set in advance requirement to accommodate the change of compensation formulas or other requirements established by payors.

Response: We decline to revise the requirement as requested by the commenters. As a safeguard against gaming or manipulating a value-based arrangement to reward referrals, we require in the final meaningful downside financial risk exception that the methodology used to determine the amount of the remuneration is set in advance of the undertaking of the value-based activities for which the remuneration is paid. We interpret this requirement in the same way as the requirement found throughout the exceptions to the physician self-referral law that compensation (or a formula for the compensation) is set in advance before the furnishing of the items or services for which the compensation is to be paid. In the final meaningful downside risk exception, we are requiring only that the *methodology* used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid. Parties need not know the ultimate *amount* of remuneration under the value-based arrangement. Thus, prior to the commencement of a value-based arrangement, if the parties agree that a physician will be paid $10 for each completed patient assessment (assuming the completion of the patient assessment qualifies as a ''value-based activity''), the methodology for determining the amount of the physician's remuneration is set in advance. If the parties later determine to increase the payment to $12 for each completed patient assessment, the revised remuneration would be considered set in advance, provided that the new remuneration terms are effective on a prospective basis only. We explore our policies regarding compensation that is set in advance with respect to outcome measures in our discussion of the value-based arrangements exception at § 411.357(aa)(3) in section II.A.1.2.b.(3). and more generally in section II.D.5. of this final rule.

(3) Value-Based Arrangements (§ 411.357(aa)(3))

The transformation to a value-based health care delivery and payment system is heavily dependent on physician engagement. As we noted in the proposed rule, commenters on the CMS RFI stated that, because physician decisions drive the overwhelming majority of all health care spending and patient outcomes, it is not possible to transform health care without a strong, aligned partnership between entities furnishing designated health services and physicians (84 FR 55783). Those commenters noted that this alignment of financial interests is key to the behavior shaping necessary to succeed in a value-based payment system. They also asserted that permitting physicians and physician groups (especially smaller practices that are not used to risk-sharing or are too small to absorb downside financial risk) to assume only upside risk—or, for that matter, no financial risk—would encourage more physicians to participate in care coordination activities now while they continue to build toward entering into two-sided risk-sharing arrangements. In consideration of these and similar comments, as well as our belief that bold reforms to the physician self-referral regulations are necessary to foster the delivery of coordinated patient care and achieve the Secretary's vision of transitioning to a truly value-based health care delivery and payment system, we proposed an exception at § 411.357(aa)(3) for compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the value-based enterprise or any of its VBE participants (the ''value-based arrangement exception'') (84 FR 55783).

As proposed, the value-based arrangement exception would permit both monetary and nonmonetary remuneration between the parties, although we considered whether to limit the scope of the exception to nonmonetary remuneration only and sought comment regarding the impact such a limitation may have on the transition to a value-based health care delivery and payment system (84 FR 55783). The final exception is not limited to the provision of only nonmonetary compensation. We also proposed to include in the value-based arrangement exception certain requirements that were included in the proposed meaningful downside financial risk exception, some of which were also included in the proposed full financial risk exception (84 FR 55783). We stated that we would interpret these requirements in the same way as in the proposed full financial risk and meaningful downside financial risk exceptions, and included them in the value-based arrangement exception for the same reasons articulated with respect to those exceptions. These requirements are: The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population; remuneration is not provided as an inducement to reduce or limit medically necessary items or services to a patient in the target patient population; remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement; the methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided; and records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request (84 FR 55783).

Because the exception at proposed § 411.357(aa)(3) would be applicable even to value-based arrangements where neither party, but especially not the physician, has undertaken any downside financial risk, we stated that safeguards beyond those included in the meaningful downside financial risk exception are necessary to protect against program or patient abuse (84 FR 55783). To address this, we proposed to replace the requirement that remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement with a requirement that remuneration is not conditioned on the volume or value of referrals of *any* patients, including patients in the target patient population, to the entity or the volume or value of *any* other business generated, including business covered by the value-based arrangement, by the physician for the entity. We did not propose to include a requirement that the remuneration is not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the entity. We sought comments regarding this alternative proposal; the interplay of the alternative requirement with our longstanding policy that the entity of which the physician is a *bona fide* employee or independent contractor, or that is a party to a managed care contract with the physician, may direct the physician's referrals to a particular provider, practitioner, or supplier, as long as the compensation arrangement meets specified conditions designed to preserve the physician's judgment as to the patient's best medical interests, avoid interfering in an insurer's operations, and protect patient choice; and whether including such an alternative requirement would impede parties' ability to achieve the value-based purposes on which their value-based arrangement is premised if the entity cannot direct referrals as historically permitted. We are finalizing the proposed safeguards that are also included in the meaningful downside risk exception at § 411.357(aa)(2), but we are not finalizing the alternative proposal regarding the conditioning of remuneration. Final § 411.357(aa)(3)(ix) requires that the remuneration under the value-based arrangement is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement. However, we are finalizing a requirement regarding patient choice, which is included in the regulations for all three of the value-based exceptions. See section II.B.4. of this final rule for a complete discussion of our interpretation of this requirement.

In addition, we proposed requirements in the exception at § 411.357(aa)(3) that the value-based arrangement is set forth in writing and signed by the parties, and that the writing includes a description of the value-based activities to be undertaken under the arrangement; how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; the target patient population for the arrangement; the type or nature of the remuneration; the methodology used to determine the amount of the remuneration; and the performance or quality standards against which the recipient of the remuneration will be measured, if any (84 FR 55783). We believe that the documentation requirements are self-explanatory. We stated that, although we expect that parties would plan to satisfy the writing requirement in advance of the commencement of the value-based arrangement, the special rule at § 411.354(e)(3) (modified, in part, from existing § 411.353(g)(1)(ii)) would apply. We are finalizing our proposal regarding the writing and signature requirements in the exception at § 411.357(aa)(3). We remind readers that the value-based purpose of the arrangement must relate to the value-based enterprise as a whole (which, as noted previously in section II.A.2.a. of this final rule, may be the two parties to the value-based arrangement), and that the exception will not protect a ''side'' arrangement between two VBE participants that is unrelated to the goals and objectives (that is, the value-based purposes) of the value-based enterprise of which they are participants, even if the arrangement itself serves a value-based purpose.

We also proposed to require that the performance or quality standards against which the recipient of the remuneration will be measured, if any, are objective and measurable, and that such standards must be determined prospectively, with any changes to the performance or quality standards set forth in writing and applicable only prospectively (84 FR 55784). Because commenters expressed concern regarding the term ''performance or quality standards,'' and in an effort to reduce burden on stakeholders by aligning our terminology with OIG, we are modifying this requirement to apply to ''outcome measures'' rather than ''performance or quality standards'' and defining ''outcome measure'' at § 411.357(aa)(3)(xii) to mean a benchmark that quantifies: (A) Improvements in or maintenance of the quality of patient care; or (B) reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care. Final § 411.357(aa)(3)(ii) requires that the outcome measures against which the recipient of remuneration will be assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support. To promote clarity, we discuss our proposals and respond to comments on our proposals regarding the performance or quality standards against which a recipient of remuneration will be assessed in terms of the ''outcome measures'' against which the recipient of the remuneration will be assessed. We discuss this modification more fully below.

We recognize that outcome measures may not be applicable to all value-based arrangements—for example, an arrangement under which a hospital provides needed infrastructure to a physician in the same value-based enterprise may not require the physician to meet specific outcome measures in order to receive or keep the infrastructure items or services. However, if the value-based arrangement does include outcome measures that relate to the receipt of the remuneration—for example, an arrangement to share the internal cost savings achieved if the physician meaningfully participates in the hospital's quality and outcomes improvement program and reaches or exceeds predetermined benchmarks for his or her personal performance or quality measurement—such outcome measures must be determined in advance of their implementation. The exception would not protect arrangements where the outcome measures are set retrospectively (84 FR 55784). In the proposed rule, to align with OIG's proposals, we considered whether to require that outcome measures be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery (84 FR 55784). We sought comment regarding whether we should include this as a requirement of the value-based arrangement exception and the burden or cost of including such a requirement. As discussed more fully below, we are not including a requirement in this final rule that outcome measures must be designed to drive meaningful improvements in physician performance, quality, health outcomes,

or efficiencies in care delivery in this final rule.

As we stated in the proposed rule, we expect that, as a prudent business practice, parties would monitor their arrangements to determine whether they are operating as intended and serving their intended purposes—regardless of whether the arrangements are value-based—and have in place mechanisms to address identified deficiencies, as appropriate (84 FR 55784). We explained that there is an implicit ongoing obligation for an entity to monitor each of its financial relationships with a physician for compliance with an applicable exception. In general, if a physician has a financial relationship with an entity that does not satisfy all the requirements of an applicable exception (after applying any special rules), section 1877(a)(1)(A) of the Act prohibits the physician from making a referral to the entity for the furnishing of designated health services for which payment may otherwise be made under Medicare, section 1877(a)(1)(B) of the Act prohibits the entity from presenting or causing to present a claim under Medicare for the designated health services furnished pursuant to a prohibited referral, and section 1877(g)(1) of the Act prohibits Medicare from making payment for a designated health service that is provided pursuant to a prohibited referral. Thus, parties must ensure the compliance of their financial relationship with an applicable exception at the time the physician makes a referral for designated health service(s).

In the proposed rule, we discussed at length the importance of monitoring arrangements that implicate the physician self-referral law (84 FR 55784). More specifically, we discussed the implicit ongoing compliance monitoring obligation for arrangements that would qualify for protection under the value-based arrangement exception at § 411.357(aa)(3). We provided a detailed example of appropriate monitoring of a value-based arrangement for compliance with the proposed exception at § 411.357(aa)(3), including the consequences of value-based activities that can no longer be considered to be reasonably designed to achieve the value-based purpose(s) of a value-based enterprise (84 FR 55784 through 55785). We considered whether to include program integrity safeguards that: (1) Require the value-based enterprise or the VBE participant providing the remuneration to monitor to determine whether the value-based activities under the arrangement are furthering the value-based purpose(s) of the value-based enterprise; and (2) if the value-based activities will be unable to achieve the value-based purpose(s) of the arrangement, require the physician to cease referring designated health services to the entity, either immediately upon the determination that the value-based purpose(s) will not be achieved through the value-based activities or within 60 days of such determination (84 FR 55785). We sought comment regarding whether we should include these as requirements of the value-based arrangement exception, how parties could monitor for achievement of value-based purposes, and the burden or cost of including such a requirement. Specifically, we sought comment regarding whether we should require that monitoring should occur at specified intervals and, if so, what the intervals should be. Recognizing that cost savings, in particular, may take an extended period of time to achieve, we also sought comment regarding whether to impose time limits with respect to a value-based enterprise's or VBE participant's determination that the value-based purpose of the enterprise will not be achieved through the value-based activities required under the arrangement; that is, require that the value-based purpose must be achieved within a certain timeframe, such as 3 years, and, if it is not, the value-based purpose would be deemed not achievable through the value-based activities required under the arrangement.

As explained in our response to comments below, we are including an explicit monitoring requirement at final § 411.357(aa)(3)(vii). Parties seeking to utilize the value-based arrangement exception (or the value-based enterprise in which they participate) must monitor the value-based arrangement no less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, to determine whether the parties have furnished the value-based activities required under the arrangement, and whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise. If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. The parties may do so by terminating the value-based arrangement or by modifying the arrangement to terminate the ineffective value-based activity after completion of the monitoring. If the parties complete the required action within the applicable timeframe, the ineffective value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise during the entire period during which it was undertaken by the parties. In addition, during the same timeframes, either the value-based enterprise or one or more of the parties to the arrangement must monitor progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed. If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring. If the parties fail to monitor outcome measures within the prescribed timeframes, or fail to terminate or replace an unattainable outcome measure within the prescribed timeframe, the value-based arrangement will no longer satisfy the requirements of the exception at § 411.357(aa)(3). We emphasize that parties may amend their value-based arrangements to address identified deficiencies at any time, provided that the amendments are prospective only, including any amendments to the compensation terms of the arrangement. We refer readers to section II.E.1. of this final rule for a discussion of the provisions on amending arrangements newly codified at § 411.354(d)(1).

We believe that requiring immediate termination of a value-based arrangement due to an ineffective value-based activity would be counterproductive to the underlying goal of encouraging the transition to a value-based health care delivery and payment system. We are providing for the noted ''grace periods'' because we recognize that parties to a value-based arrangement may need time to address an ineffective value-based activity identified through their monitoring. As discussed in the proposed rule, the physician self-referral law would prohibit a physician from making referrals to an entity, and prohibit the entity from submitting claims for designated health services referred by the physician, if the value-based arrangement does not satisfy all the requirements of an applicable exception at the time of the referral. This includes the requirement that the value-based activities undertaken under the arrangement, by definition, are reasonably designed to achieve one or more value-base purposes of the value-

based enterprise (84 FR 55785). We believe that it is necessary to allow parties an appropriate amount of time to address the findings of their monitoring without fear of violating the physician self-referral law. We also believe that a policy under which parties that act quickly to rectify the ineffectiveness of their value-based activities will not run afoul of the physician self-referral law does not pose a risk of program or patient abuse. As described above, we are finalizing a policy under which a value-based activity will be deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise during the entire period during which it was undertaken by the parties if the parties terminate the arrangement within 30 consecutive calendar days after the completion of the required monitoring or modify their arrangement to terminate the ineffective value-based activity within 90 consecutive calendar days after completion of the monitoring. Similarly, we are finalizing a policy that provides for 90 consecutive calendar days for parties to terminate or replace an outcome measure that their monitoring indicates is unattainable.

To illustrate the monitoring requirement at final § 411.357(aa)(3)(vii) with respect to monitoring of value-based activities, we apply it here in the context of the scenario described in the proposed rule (84 FR 55784 through 55785). Assume a hospital revised its care protocol for screening for a certain type of cancer to incorporate newly issued guidelines from a nationally recognized organization. The new guidelines, and the revised protocol, no longer support a single screening modality for the disease. Instead, the organization recommends screening by combining two modalities to achieve more accurate results. The revised guidelines and hospital care protocol are intended to improve the quality of care for patients by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results (which can be frequent for single-modality screening for the disease). The hospital observes that most community physicians continue to refer patients to the hospital for single-modality screening. To align referring physician practices with the hospital's revised care protocol, the hospital offers to pay physicians $10 for each instance that they order dual-modality screening in accordance with the revised care protocol during a 2-year period beginning on January 1, 2021. The hospital expects that it would take approximately 2 years to shape physician behavior to always follow the recommended care protocol (except when not medically appropriate for the particular patient). Assume that both single-modality and dual-modality screening are designated health services payable by Medicare. In this illustration, the value-based enterprise is the hospital and identified community physicians. (The hospital and the community physicians could also be part of a larger value-based enterprise.) The target patient population is patients in the hospital's service area that receive screening for the particular disease. The value-based activity is adherence with the hospital's revised care protocol by ordering dual-modality screening instead of single-modality screening. The value-based purpose of the value-based enterprise is to improve the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results.

At its inception, provided that an arrangement between the hospital and a physician satisfies all the requirements of § 411.357(aa)(3), the physician's referrals of designated health services to the hospital and the hospital's submission of claims to Medicare for the designated health services referred by the physician would not violate the physician self-referral law. However, assume that during the first year of the arrangement, the hospital determines through its monitoring that its data analysis indicates that the use of dual-modality screening not only does not result in earlier detection of cancer, but results in more false positive results, invasive biopsies, and unnecessary treatment than single-modality screening. As a result, the hospital determines that the use of dual-modality screening, despite the nationally-recognized recommendations, will not achieve the goal of improving the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results. The compliance monitoring, which occurred in the first year of the arrangement, has identified that the continuation of the value-based activity, dual-modality screening, is no longer expected to further the value-based purpose of improving the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results. Once the hospital has identified the ineffective value-based activity, the hospital has two options to maintain compliance with the physician self-referral law. Under final § 411.357(aa)(3)(vii)(B), the parties could terminate the arrangement within 30 consecutive calendar days of the date of completion of the monitoring indicating that the value-based activity was ineffective, or the parties could modify the arrangement to terminate the ineffective value-based activity within 90 consecutive calendar days of completion of the monitoring and, if they choose, replace it with a different value-based activity with prospective applicability. If the parties fail to take one of these actions, the physician would be prohibited from making referrals of any designated health services to the hospital from the date the hospital became aware that its value-based arrangement no longer satisfied the requirements of § 411.357(aa)(3) (unless the arrangement satisfies the requirements of another applicable exception to the physician self-referral law, which it likely would not). In addition, the hospital would be prohibited from submitting claims to Medicare for any improperly referred designated health services. The parties' lack of knowledge does not affect compliance with the physician self-referral law. The hospital's (or value-based enterprise's) failure to monitor as required under our final regulations for progress toward achievement of the value-based purpose of the value-based enterprise would not nullify the parties' noncompliance with the physician self-referral law. The physician's referrals would be prohibited due to the fact that adherence to the revised care protocol could not, in fact, achieve the value-based purpose of the value-based enterprise and would no longer qualify as a ''value-based activity'' as that term is defined at final § 411.351. In turn, the arrangement would not qualify as a ''value-based arrangement'' and the exception at § 411.357(aa)(3) would no longer be available to protect the physician's referrals.

In the proposed rule, we also considered whether to require the recipient of any nonmonetary remuneration under a value-based arrangement to contribute at least 15 percent of the donor's cost of the nonmonetary remuneration (84 FR 55785 through 55786). We stated that requiring financial participation by a recipient of nonmonetary remuneration under a value-based arrangement would help ensure that the nonmonetary remuneration is appropriate and beneficial for the achievement of the value-based purpose(s) of the value-based enterprise, as well as ensuring

that the recipient will actually use the nonmonetary remuneration. However, we also stated our concern that such a requirement could inhibit the adoption of value-based arrangements. As discussed in section II.D.11.d.(1). of this final rule, even though many commenters asserted that the 15 percent contribution requirement under the existing exception for EHR items and services is burdensome to some recipients and acts as a barrier to adoption of EHR technology, we are retaining the 15 percent contribution requirement for the existing EHR exception as an important program integrity safeguard where the compensation arrangement between the parties is not a value-based arrangement. We are concerned, however, that requiring a 15 percent contribution from the recipient of nonmonetary compensation under a value-based arrangement could inhibit the goal of transitioning to a value-based health care delivery and payment system. We are not including a contribution requirement in the value-based arrangement exception finalized in this final rule.

We received the following comments and our responses follow.

Comment: The vast majority of commenters supported the adoption of a value-based arrangement exception and urged CMS to finalize the exception without modification in order to support the transition to a value-based health care delivery and payment system. Commenters expressed appreciation for the creation of a value-based exception with no downside risk, asserting that the exception will be beneficial to rural providers, small practices, and others wanting to explore value-based health care delivery and payment, but not yet well-positioned to take on meaningful financial risk. A few commenters suggested that the value-based arrangement exception is complex and burdensome, and could act as a deterrent to participation in value-based health care. A small number of commenters urged us not to finalize the value-based arrangement exception, citing program integrity concerns.

Response: We agree with the commenters that the exception at § 411.357(aa)(3) is necessary to facilitate robust participation in a value-based health care delivery and payment system. We are finalizing the exception with the modifications discussed above and in our response to other comments in this section II.A.2. Although we appreciate the program integrity concerns raised by some commenters, we are confident that the integrated approach to safeguards against program and patient abuse found in the value-based definitions and exceptions will ensure that even ''no risk'' value-based arrangements that satisfy all the requirements of the definitions and the requirements of § 411.357(aa)(3) will not pose a risk of program or patient abuse.

Comment: The majority of commenters urged CMS not to limit the value-based arrangement exception to nonmonetary remuneration. The commenters pointed to value-based arrangements commonplace in the industry, such as payment for adherence to care protocols or shared savings models that utilize cash incentives to shape physician behavior, improve quality, and reduce waste. One commenter expressed concern that, by limiting the type of remuneration permissible under the exception, CMS would create a complicated patchwork of protections depending on the type of remuneration at issue.

Response: We are not limiting the value-based arrangement exception to nonmonetary remuneration only. Limiting the exception to nonmonetary remuneration could undermine the Secretary's goal of robust participation in a value-based health care delivery and payment system by artificially restricting the types of arrangements that are appropriate for protection from the prohibitions of the physician self-referral law.

Comment: Commenters nearly universally opposed the inclusion of a contribution requirement for nonmonetary remuneration provided under a value-based arrangement. Commenters asserted that such a contribution requirement would create a barrier to widespread participation in a value-based health care delivery and payment system. Many commenters echoed our concerns in the proposed rule that a contribution requirement for nonmonetary remuneration would unfairly impact small and rural physician practices, providers, and suppliers that cannot afford the contribution (84 FR 55786).

Response: We agree with the commenters that requiring a 15 percent contribution for nonmonetary remuneration provided under a value-based arrangement could create barriers to the transition to a value-based health care delivery and payment system, particularly for small and rural physician practices, providers, and suppliers. The final value-based arrangement exception does not require a contribution for nonmonetary remuneration.

Comment: A few commenters expressed concern regarding the requirement that a value-based arrangement must be set forth in writing and signed by the parties. These commenters viewed these documentation requirements as unnecessary and creating an administrative burden. A few commenters requested confirmation that the writing requirements of § 411.357(aa)(3) may be satisfied through a collection of contemporaneous documents evidencing the conduct between the parties and that a single, formal contract is not required. These same commenters also requested confirmation that the special rule for signature requirements at § 411.354(e) (formerly at § 411.353(g)) would apply to value-based arrangements. One commenter requested that we eliminate the signature requirement from the value-based arrangement exception to avoid what the commenter called ''technical violations.''

Response: We do not consider the documentation requirements under the final value-based arrangement exception burdensome. As discussed above, we view the documentation requirements as self-explanatory and a necessary program integrity safeguard. As we have stated in prior rulemakings, we believe that it is a usual and customary business practice to document and sign arrangements and the requirements of the exceptions to the physician self-referral law do not add burden to these practices. (*See,* for example, 83 FR 59993.) Nothing in the final value-based arrangement exception at § 411.357(aa)(3)—or any other exception to the physician self-referral law—requires a single formal contract to satisfy the writing requirement of the exceptions.

Comment: Several commenters raised concerns with our discussion in the proposed rule that parties have an implicit obligation to monitor their arrangements for compliance with the physician self-referral law (84 FR 55784). These commenters asserted that the use of the term ''implicit'' introduces ambiguity that is not appropriate for a strict liability statute. The commenters requested that any monitoring obligations, including the scope and frequency of the monitoring, be clearly stated in the regulations. A few of the commenters suggested that CMS provide flexibility in monitoring and assessing progress of a value-based arrangement, asserting that the monitoring requirement should be tailored to the resources and sophistication of the parties to the value-based arrangement. Some commenters stated that monitoring for compliance with the requirements of an

applicable exception at the outset of an arrangement and upon renewal of the arrangement is a common industry practice and suggested that we adopt a similar policy for monitoring value-based arrangements.

Response: The commenters' statements regarding parties' obligations to monitor for ongoing compliance with the physician self-referral law are surprising, as are their statements that references to this implicit obligation would introduce ambiguity into their ability to utilize the value-based arrangement exception. Our expectation of monitoring for ongoing compliance in the context of the physician self-referral law is not a new concept. As we stated in Phase II, section 1877 of the Act is clearly intended to make entities responsible for monitoring their compensation arrangements with physicians (69 FR 16112). As discussed above, the core principle of the physician self-referral law is that, if a physician has a financial relationship with an entity that does not satisfy all the requirements of an applicable exception (after applying any special rules), section 1877(a)(1)(A) of the Act prohibits the physician from making a referral to the entity for the furnishing of designated health services for which payment may otherwise be made under Medicare, section 1877(a)(1)(B) of the Act prohibits the entity from presenting or causing to present a claim under Medicare for the designated health services furnished pursuant to a prohibited referral, and section 1877(g)(1) of the Act prohibits Medicare from making payment for a designated health service that is provided pursuant to a prohibited referral. Parties must ensure the compliance of their financial relationships with an applicable exception at the time the physician makes a referral for designated health service(s).

We agree with the commenters that the government's expectations regarding monitoring of value-based arrangements should be explicitly stated in regulation text, and we are including at final § 411.357(aa)(3)(vii) a monitoring requirement that provides the guidelines requested by the commenters. Under the final regulation, the value-based enterprise or one or more of the parties to a value-based arrangement must monitor the arrangement no less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year. This timeframe coincides with that proposed by OIG in its safe harbors for value-based arrangements and finalized elsewhere in this issue of the **Federal Register**. To facilitate the assessment of ongoing compliance with the physician self-referral law, we are finalizing our proposal to require that the value-based enterprise or one or more of the parties to the value-based arrangement must monitor whether the parties have furnished the value-based activities required under the arrangement and whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise. If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. In addition, during the same timeframes, either the value-based enterprise or one or more of the parties to the arrangement must monitor progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed. If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure.

As discussed in response to the comment below, the final regulation at § 411.357(aa)(3)(vii) sets forth specific timeframes in which the parties must take action following completion of monitoring that identifies an ineffective value-based activity or that an outcome measure is unattainable during the remaining term of the arrangement. If the parties take action within the timeframe specific to the chosen action (that is, termination or modification of the value-based arrangement), a value-based activity will be deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise for the entire period during which it was undertaken by the parties. Similarly, the arrangement will not fail to satisfy the requirements of the exception at § 411.357(aa)(3) if, within 90 consecutive calendar days after completion of the monitoring, the parties terminate or replace an outcome measure determined to be unattainable. We are not prescribing in this final rule how value-based enterprises, entities, and physicians should monitor their value-based arrangements; rather, we expect value-based enterprises, entities, and physicians to design their monitoring and other compliance efforts in a manner that is appropriate for the particular value-based arrangement.

Comment: Several commenters urged us not to require termination of a value-based arrangement due to a value-based activity no longer furthering the value-based purpose of the value-based enterprise. These commenters recommended that we establish a timeframe for ''curing'' noncompliance or create a transition period that allows the parties to the value-based arrangement to redesign or replace the deficient value-based activity, with a couple commenters suggesting 90 days for that timeframe. A few commenters suggested giving parties the option of terminating the arrangement in its entirety or allowing them to implement a written plan to remediate the noncompliance no later than 60 days from the date they determine that the value-based activities are unable to achieve the value-based purposes. One commenter requested that we adopt a policy that an arrangement would not lose protection under the value-based arrangement exception for a period of 12 months from the date of commencement of the arrangement as long as the value-based activities were reasonably designed to achieve the value-based purpose at its outset. Some commenters suggested that a policy under which a physician's referrals are considered to violate the physician self-referral law if value-based activities do not immediately succeed in achieving the value-based purpose(s) of the value-based enterprise would create a ''fear of failure'' that would dissuade parties from attempting to deliver health care in new and innovative value-based ways. These commenters asserted that allowing parties to cure defects in arrangements would remove the ''fear of failure'' and promote value-based health care delivery. A different commenter requested that we establish a specific timeframe for a value-based arrangement to achieve its value-based purpose without risking violation of the physician self-referral law.

Response: As discussed above, if parties to a value-based arrangement, through monitoring efforts or otherwise, determine that a value-based activity no longer furthers the value-based purpose(s) of the value-based enterprise, the parties may either terminate the arrangement or modify the arrangement to remove the ineffective value-based activity. The commenters mistakenly assumed that termination of a value-based arrangement is required if a value-based activity is no longer reasonably designed to further the value-based purpose(s) of the value-based enterprise. Our proposal required the cessation of the physician's referrals of designated health services, either immediately or within 60 days of the determination that the value-based activities would be

unable to achieve the value-based purpose(s) of the value-based enterprise. We did not intend to prohibit modification of arrangements that would allow continuation of physician referrals.

We recognize that the design and implementation of value-based arrangements require a certain level of fluidity, although we are not persuaded to implement a 12-month ''deeming'' timeframe under which a value-based arrangement would be deemed to satisfy the requirement that its value-based activities are reasonably designed to further the value-based purpose(s) of the value-based enterprise for a period of 12 months from their implementation. Such a policy would permit parties with actual knowledge that the value-based activities will be unable to achieve the value-based purpose(s) to make referrals and submit claims for designated health services potentially much longer than we believe is necessary to make appropriate modifications to their arrangement.

We agree with the commenters that identified 90 days as the amount of time that parties would need to make adjustments to their value-based arrangements when they are aware that a value-based activity will no longer further the value-based purpose(s) of the value-based enterprise. We note that this timeframe is consistent with other timeframes for remediating temporary noncompliance, documentation deficiencies, and other discrepancies in our regulations. We do not believe that parties that elect to terminate their value-based arrangement would need as much time. Accordingly, we have established in our final regulation timeframes in which the parties to a value-based arrangement may address any identified deficiencies with their value-based activities without running afoul of the physician self-referral law. Under the final regulations at § 411.357(aa)(3)(vii)(B)(*1*) and (*2*), a value-based activity will be deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise for the entire period during which it was undertaken if the parties terminate the arrangement within 30 consecutive calendar days or modify the arrangement within 90 consecutive calendar days after completion of the monitoring. We believe that parties to a value-based arrangement that identify ineffective value-based activities should be able to decide whether to terminate the entire arrangement and effectuate such a termination within 30 consecutive calendar days of identifying the ineffective value-based activities. In order to protect against program and patient abuse that could arise with an unlimited timeframe in which to terminate specific value-based activities, we are establishing at § 411.357(aa)(3)(vii)(B)(*2*) a 90-day timeframe for the termination of value-based activities that are not expected to further the value-based purpose(s) of the value-based enterprise. To maintain consistency with other regulations that require remedial action within certain timeframes, the regulation requires that the termination of the arrangement or the ineffective value-based activity must occur within the specified number of *consecutive calendar days.* The provisions of final § 411.357(aa)(3)(vii)(B)(*1*) and (*2*) should address the concerns raised by the commenters without risking program or patient abuse.

Comment: Several commenters inquired about the proposed requirement that performance or quality standards against which the recipient of the remuneration will be measured, if any, are objective and measurable. The commenters generally supported a requirement that performance or quality standards must be objective and measurable, but requested additional guidance regarding what qualifies as a ''performance or quality standards.'' The commenters generally opposed our alternative proposal to require that performance or quality standards must be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery. Commenters asserted that this alternative proposal and the use of the language ''designed to drive meaningful improvements'' created ambiguity that would hinder participation in value-based arrangements.

Response: The final regulations at § 411.357(aa)(3)(i)(F) and (ii) replace the term ''performance and quality standards'' with the term ''outcome measures.'' The final exception requires at § 411.357(aa)(3)(ii) that the outcome measures against which the recipient of remuneration under a value-based arrangement will be measured, if any, are objective and measurable, and any changes to the outcome measures must be made prospectively and set forth in writing. We have also added a new paragraph (xii) that defines ''outcome measure,'' for purposes of the value-based arrangement exception, to mean a benchmark that quantifies: (A) Improvements in or maintenance of the quality of patient care; or (B) reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care. This definition is intended to align with OIG's final regulations. We are sympathetic to commenters' concerns regarding the difficulty in ascertaining that a measure is designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery. We are not adopting our alternative proposal to require that outcome measures against which recipients of remuneration are measured are designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery.

Comment: Many commenters appear to have misinterpreted the meaning of the requirement at § 411.357(aa)(3)(ii) that the outcome measures against which the recipient of the remuneration will be measured, if any, are objective and measurable, and any changes to the outcome measures must be made prospectively and set forth in writing. The commenters interpreted this provision to require the inclusion of outcome measures in all value-based arrangements and questioned whether that is practical. Some of the commenters noted that preventive care and primary care services do not necessarily lend themselves to outcome measures, asserting that benefits of these services may not be immediately measureable.

Response: The requirements at final § 411.357(aa)(3)(i)(F) and (ii) specifically include the language ''if any'' to indicate that outcome measures are not required in every value-based arrangement. We recognize that outcome measures may not be available for or applicable to certain value-based activities. For instance, the adoption of the same EHR system or the completion of training on the EHR system are potential value-based activities that likely would not have an associated outcome measure. However, if outcome measures are included as part of the value-based arrangement, those outcome measures must be objective and measurable and determined prospectively. In addition, under final § 411.357(aa)(3)(vii), either the value-based enterprise or one or more of the parties to the arrangement must monitor progress toward attainment of the outcome measure(s) against which the recipient of the remuneration is assessed. If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

Comment: A few commenters stated that they interpreted the requirement that the outcome measures against which the recipient of the remuneration will be measured, if any, are objective and measurable, and any changes to the outcome measures must be made prospectively and set forth in writing to mean that constant improvement or the achievement of the outcome measures is required. Some of the commenters also interpreted this requirement to mean that parties to a value-based arrangement may not substitute outcome measures or make other adjustments to the outcome measures during the term of the value-based arrangement. These commenters asserted that it is common for parties to value-based arrangements to reevaluate outcome measures and make modifications necessary to continue moving towards achievement of the purposes of the value-based enterprise. The commenters sought confirmation that parties are permitted to modify their arrangements, including making changes to outcome measures, and make other necessary adjustments over the course of a value-based arrangement without losing the protection of the exception.

Response: The commenters may have misinterpreted the requirements of the proposed exception. We are defining ''outcome measure'' in this final rule to mean a benchmark that quantifies: (A) Improvements in or maintenance of the quality of patient care; or (B) reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care. Outcome measures are used to evaluate the provision and effectiveness of value-based activities to ensure that the value-based activities are continuing to further the value-based purposes of the value-based enterprise. Nothing in this final rule prohibits the replacement or substitution of outcome measures against which the recipient of the remuneration is measured under a value-based arrangement, provided that any changes to the outcome measures are made prospectively and set forth in writing.

For example, assume that a physician can earn incentive pay under a value-based arrangement for providing certain post-discharge follow-up services to patients in a target patient population following their discharge from the hospital, and that the value-based purpose of the value-based enterprise is to improve the quality of patient care by facilitating a smooth transition from an acute care setting to the appropriate post-acute care setting and lowering readmissions to the hospital. The physician's remuneration for providing post-discharge follow-up services under the arrangement may be, in whole or in part, dependent on whether the hospital reduces its readmission rate to 65 percent or lower for patients treated by the physician. The ''outcome measure'' is the readmission rate. If the parties wish to revise this outcome measure—for example, because the hospital realizes that a readmission rate of 65 percent or lower is too easily attainable or is unrealistic given the severity of the medical conditions of the patients in the target patient population and, specifically, the patients treated by the physician—they may make necessary adjustments to the readmission measure, provided any changes to the measure are prospective only and set forth in writing. It would not be permissible to change the outcome measure to a lower, more attainable readmission percentage and apply that new outcome measure retroactively in order to allow the physician to earn the incentive payment under the value-based arrangement as originally designed. To the extent that commenters were concerned that parties may not amend their value-based arrangements to require more or different value-based activities than those included in the arrangement as originally designed, we emphasize that nothing in final § 411.357(aa)(3) prohibits termination or substitution of value-based activities to be undertaken under a value-based arrangement, provided that all modifications to the value-based arrangement are effective prospectively and comply with any applicable regulations regarding the modification of compensation arrangements.

(4) Indirect Compensation Arrangements to Which the Exceptions at § 411.357(aa) Are Applicable (§ 411.354(c)(4))

The prohibitions of section 1877 of the Act apply if a physician (or an immediate family member of a physician) has an ownership or investment interest in an entity or a compensation arrangement with an entity. For purposes of the physician self-referral law, a compensation arrangement is any arrangement involving direct or indirect remuneration between a physician (or an immediate family member of the physician) and an entity, and remuneration means any payment or other benefit made directly, indirectly, overtly, covertly, in cash, or in kind. (*See* §§ 411.351 and 411.354(c).) In Phase I, we finalized regulations that define when an indirect compensation arrangement exists between a physician and the entity to which he or she refers designated health services (66 FR 864). For purposes of applying these regulations, in the FY 2009 IPPS final rule, we finalized additional regulations that deem a physician to stand in the shoes of his or her physician organization if the physician has an ownership or investment interest in the physician organization that is not merely a titular interest (73 FR 48693). These regulations are found at § 411.354(c)(2) and (3).

Under our current regulations, if an indirect compensation arrangement exists, the exception for indirect compensation arrangements at § 411.357(p) is available to protect the compensation arrangement. In addition, if the entity with which the physician has the indirect compensation arrangement is a MCO or IPA, the exception at § 411.357(n) is also available to protect the compensation arrangement. If all the requirements of one of the applicable exceptions are satisfied, the physician would not be barred from referring patients to the entity for designated health services and the entity would not be barred from submitting claims for the referred services. No other exception in § 411.357 is applicable to indirect compensation arrangements. However, the parties may elect to protect individual referrals of and claims for designated health services using an applicable exception in § 411.355 of our regulations.

As we stated in the proposed rule (84 FR 55786), an unbroken chain of financial relationships described in § 411.354(c)(2)(i) may include a value-based arrangement as defined at § 411.351 in this final rule. Thus, an unbroken chain of financial relationships that includes a value-based arrangement could form an ''indirect compensation arrangement'' for purposes of the physician self-referral law if the circumstances described in § 411.354(c)(2)(ii) and (iii) also exist. Unless the entity furnishing the designated health services is a MCO or IPA, the parties would have to rely on the exception at § 411.357(p), which includes requirements not found in the exceptions for value-based arrangements at § 411.357(aa), in order to ensure the permissibility of *all* the physician's referrals to the entity (assuming no other financial relationships exist between the parties). (If the parties elect to utilize a ''services'' exception at § 411.355, designated health services are protected only on a service-by-service basis, and satisfaction of the requirements of an applicable exception permits only the referral of and claims submission for the

particular designated health service that satisfied the requirements of the exception.) As commenters on the CMS RFI noted and commenters on the proposed rule confirmed, because compensation to the physician under a value-based arrangement could take into account the volume or value of referrals or other business generated by the physician for the entity or may not be fair market value for specific items or services provided by the physician, an indirect compensation arrangement that includes a value-based arrangement in the unbroken chain of financial relationships that forms the indirect compensation arrangement may be unable to satisfy the requirements of § 411.357(p). To avoid a blanket prohibition on indirect compensation arrangements that enhance value-based health care delivery and payment, we are finalizing our proposal to make additional exceptions available to certain indirect compensation arrangements that include a value-based arrangement in the unbroken chain of financial relationships described in § 411.354(c)(2)(i).

As described in section II.A.2.b. of this final rule, we are finalizing exceptions available only to compensation arrangements that qualify as value-based arrangements. Although the exceptions do not limit their applicability to value-based arrangements directly between a physician and the entity to which he or she refers designated health services, the definition of ''value-based arrangement'' finalized at § 411.351 establishes that the only potential parties to a value-based arrangement are the value-based enterprise and VBE participants. In order to fully support the transition to a value-based health care delivery and payment system, we believe that it is important to make the exceptions at § 411.357(aa) applicable to certain indirect compensation arrangements that include a value-based arrangement in the unbroken chain of financial relationships described in § 411.354(c)(2)(i). Following review of the comments on our proposed alternative approaches for addressing indirect compensation arrangements in which one link in the unbroken chain of financial relationships between an entity and a physician is a value-based arrangement, with technical revisions to the proposed regulation text, we are finalizing our primary proposal to make the exceptions at § 411.357(aa) applicable to certain indirect compensation arrangements that include a value-based arrangement in the unbroken chain of financial relationships described in § 411.354(c)(2)(i). Specifically, under the regulation finalized at § 411.354(c)(4)(iii), the exceptions at § 411.357(aa) are available to protect the physician's referrals to the entity when an indirect compensation arrangement (as defined at § 411.354(c)(4)(2)) includes a value-based arrangement (as defined at § 411.351) to which the physician (or the physician organization in whose shoes the physician stands) is a direct party. To be clear, the link closest to the physician may not be an ownership interest; it must be a compensation arrangement that meets the definition of value-based arrangement finalized at § 411.351.

Under this final rule, parties would first determine if an indirect compensation arrangement exists and, if it does, determine whether the compensation arrangement to which the physician (or the physician organization in whose shoes the physician stands) is a direct party qualifies as a value-based arrangement. If so, the exceptions at § 411.357(aa) for value-based arrangements would be applicable. To illustrate, assume an unbroken chain of financial relationships between a hospital and a physician that runs: Hospital—(owned by)—parent organization—(owns)—physician practice—(employs)—physician. Thus, the links in the unbroken chain are ownership or investment interest—ownership or investment interest—compensation arrangement. For purposes of determining whether an indirect compensation arrangement exists between the physician and the hospital, under § 411.354(c)(2)(ii), we would analyze the compensation arrangement between the physician practice and the physician. Assume also that the compensation paid to the physician under her employment arrangement varies with the volume or value of her referrals to the hospital because she is paid a bonus for each referral for designated health services furnished by the hospital, provided that she adheres to redesigned care protocols intended to further one or more value-based purposes (as defined at § 411.351 in this final rule). Finally, assume that the hospital has actual knowledge that the physician receives aggregate compensation that varies with the volume or value of her referrals to the hospital. The unbroken chain of financial relationships establishes an indirect compensation arrangement; therefore, in order for the physician to refer patients to the hospital for designated health services and for the hospital to submit claims to Medicare for the referred designated health services, the indirect compensation arrangement must satisfy the requirements of an applicable exception. Under the final regulation at § 411.354(c)(4)(iii), if the compensation arrangement in this example between the physician practice and the physician qualifies as a value-based arrangement (as defined at § 411.351 in this final rule), the exceptions at § 411.357(aa) would be available to protect the value-based arrangement (that is, the indirect compensation arrangement) between the hospital and the physician. (The parties could also utilize an applicable exception in § 411.355 to protect individual referrals for designated health services or the exception at § 411.357(p) to protect the indirect compensation arrangement between the hospital and the physician, but it is unlikely that all the requirements of § 411.357(p) would be satisfied in this hypothetical fact pattern.)

In the proposed rule, we described an alternative proposal under which we would define ''indirect value-based arrangement'' and specify in regulation that the exceptions at § 411.357(aa) would be available to protect an indirect value-based arrangement (84 FR 55787). Under our alternative proposal, an indirect value-based arrangement would exist if: (1) Between the physician and the entity there exists an unbroken chain of any number (but not fewer than one) of persons (including but not limited to natural persons, corporations, and municipal organizations) that have financial relationships (as defined at § 411.354(a)) between them (that is, each person in the unbroken chain is linked to the preceding person by either an ownership or investment interest or a compensation arrangement); (2) the financial relationship between the physician and the person with which he or she is directly linked is a value-based arrangement; and (3) the entity has actual knowledge of the value-based arrangement in subparagraph (2). We proposed that, if an unbroken chain of financial relationships between a physician and an entity qualifies as an ''indirect value-based arrangement,'' the exceptions at § 411.357(aa) would be applicable and the requirements of at least one of the applicable exceptions must be satisfied in order for the physician to refer patients to the hospital for designated health services and for the hospital to submit claims to Medicare for the referred designated health services. Following review of the comments on our alternative approach for addressing indirect compensation arrangements in which one link in the

unbroken chain of financial relationships between an entity and a physician is a value-based arrangement, we are not finalizing the alternative proposal.

We also stated in the proposed rule that we were considering whether to exclude an unbroken chain of financial relationships between an entity and a physician from the definition of ''indirect value-based arrangement'' if the link closest to the physician (that is, the value-based arrangement to which the physician is a party) is a compensation arrangement between the physician and a pharmaceutical manufacturer; manufacturer, distributor, or supplier of DMEPOS; laboratory; pharmacy benefit manager; wholesaler; or distributor. In the alternative, we stated that we were considering whether to exclude an unbroken chain of financial relationships between an entity and a physician from the definition of ''indirect value-based arrangement'' if one of these persons or organizations is a party to any financial relationship in the chain of financial relationships. Finally, we stated that we were considering whether to include health technology companies in any such exclusion in order to align our policies with policies proposed by OIG (84 FR 55786 through 55787). We sought comment on these approaches and their effectiveness in enhancing program integrity. We are not finalizing any of the proposed restrictions on the identity of the parties to the financial relationships in the unbroken chain of financial relationships between an entity and a physician.

We received the following comments and our responses follow.

Comment: The majority of the commenters that commented on this proposal preferred our primary approach for addressing indirect compensation arrangements in which one of the financial relationships between a physician (or the immediate family member of the physician) and the entity to which the physician refers patients for designated health services is a value-based arrangement. Commenters noted that an indirect compensation arrangement that involves a value-based arrangement may not satisfy the requirements of the exception at § 411.357(p) because the compensation paid to the physician may take into account the volume or value of the physician's referrals or the other business generated by the physician for the entity, or the compensation may not meet the fair market value requirement of the exception.

Response: We are finalizing regulations at § 411.354(c)(4)(iii) to provide that the exceptions at § 411.357(aa) are applicable when an unbroken chain described in § 411.354(c)(2)(i) includes a value-based arrangement (as defined in § 411.351) to which the physician (or the physician organization in whose shoes the physician stands) is a direct party. In order to determine whether the physician's referrals to the entity with which the physician has the indirect compensation arrangement do not violate the physician self-referral law, parties would determine whether the value-based arrangement to which the physician (or the physician organization in whose shoes the physician stands) is a direct party satisfies all the requirements of one of the exceptions finalized at § 411.357(aa) (or another applicable exception). If the value-based arrangement to which the physician is a direct party is with an entity (as defined at § 411.351) other than the entity with which the physician has the indirect compensation arrangement, that direct compensation arrangement must also satisfy the requirements of an applicable exception in order for the physician to make referrals to that entity.

Comment: A few commenters expressed concern regarding our statement in the proposed rule that, besides the exception at § 411.357(p), no other exception in § 411.357 is applicable to indirect compensation arrangements (84 FR 55786). The commenters requested that we confirm that the exception at § 411.357(n) for risk-sharing arrangements is applicable to indirect compensation arrangements, including an indirect compensation arrangement that involves a value-based arrangement. One of the commenters noted that the exception for risk-sharing arrangements expressly references compensation conveyed ''directly or indirectly'' to a physician. This commenter and others asserted that the exception for risk-sharing arrangements should remain available to entities, such as hospitals, that have indirect compensation arrangements with physicians resulting from risk-sharing arrangements.

Response: Some of the commenters misunderstand the application of the exception for risk-sharing arrangements. The exception at § 411.357(n) applies to compensation arrangements between a MCO or an IPA and a physician for services provided to enrollees of a health plan, provided that the compensation arrangement qualifies as a risk-sharing arrangement. In Phase I, we established the exception at § 411.357(n) for remuneration provided pursuant to a risk-sharing arrangement *between a physician and a health plan.* There, we stated that physicians generally are compensated for services to managed care enrollees in one of three ways, the first two of which do not vary based on the volume or value of referrals: (1) A salary, in the case of a physician who is an employee; (2) a ''fee-for-service'' contractual arrangement under which the physician assumes no risk; or (3) a risk-sharing arrangement, under which the physician assumes risk for the costs of services, either through a capitation arrangement, or through a withhold, bonus, or risk-corridor approach. We noted that the first two types of compensation arrangements are eligible for the statutory exceptions for *bona fide* employment relationships and personal service arrangements,[6] while the third is potentially eligible for the exception for risk-sharing arrangements at § 411.357(n). The exception at § 411.357(n) does not apply to a compensation arrangement—whether direct or indirect—between a physician and an entity that is anything other than a MCO or IPA.

The risk-sharing arrangement between the MCO or IPA and the physician may be direct or indirect. An indirect risk-sharing arrangement would run MCO or IPA—subcontractor—physician; for example, MCO—(compensation arrangement)—hospital—(compensation arrangement)—physician. In this example, if the MCO is an ''entity'' (as defined at § 411.351), the unbroken chain of financial relationships may constitute an indirect compensation arrangement under § 411.354(c)(2). If so, the exception at § 411.357(n) would be available to protect the physician's referrals to the MCO, provided that all the requirements of the exception are satisfied. The exception for indirect compensation arrangements at § 411.357(p) would also apply. If the MCO or IPA is not itself furnishing designated health services (as described in § 411.351), it would not be an ''entity'' and, in the example above, would not have a direct or indirect compensation arrangement with the physician. (Note that, in Phase I, we clarified and significantly narrowed the situations in which a MCO will be considered an entity furnishing designated health services by refocusing the definition on the party submitting a claim to Medicare rather than the party ''providing for'' or ''arranging for'' the furnishing of designated health services

[6] In and since the publication of Phase I, we established additional regulatory exceptions that may be applicable to the first two types of compensation arrangements discussed at 66 FR 912.

for which a claim is submitted to Medicare.)

To be clear, the exception for risk-sharing arrangements at § 411.357(n) is not applicable to all risk-sharing arrangements between entities and physicians that provide services to enrollees of the same health plan. Contrary to commenters' stated understanding of the application of § 411.357(n), the exception for risk-sharing arrangements does not apply to indirect compensation arrangements between hospitals and physicians, even if both are contractors (or subcontractors) of the same MCO or IPA. In Phase II, a commenter requested confirmation that the exception at § 411.357(n) is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, or health maintenance organization. We confirmed the commenter's understanding of the applicability of the exception (69 FR 16114), and stated that all downstream entities are included. We purposefully declined to define the term ''managed care organization'' so as to create a broad exception with maximum flexibility. Although we did not in Phase II (or any subsequent rulemaking) modify the text of § 411.357(n) to extend the applicability of the exception to compensation pursuant to a risk-sharing arrangement (directly or indirectly) between a physician and any entity other than a MCO or IPA, we recognize why the commenters on the proposed rule could be under the impression that our response in the Phase II preamble was intended to do so. For this reason, we are finalizing revisions to the exception at § 411.357(n) to clarify the scope and application of the exception. The revisions are effective as of the date set forth in this final rule and apply prospectively only.

Comment: A few commenters requested that we include a reference to § 411.357(n) in the regulation text identifying which exceptions are applicable to indirect compensation arrangements that involve value-based arrangements.

Response: To clarify the applicability of the exception for risk-sharing arrangements, we are finalizing regulations at § 411.354(c)(4)(ii) and (iii)(B) that expressly state that the exception at § 411.357(n) is applicable in the case of an indirect compensation arrangement in which the entity furnishing designated health services described in § 411.354(c)(2)(i) is a MCO or IPA. If the entity with which the physician has an indirect compensation arrangement is not a MCO or IPA, the exception for risk-sharing arrangements is not applicable to the indirect compensation arrangement.

(5) Price Transparency

Price transparency is a critical component of a health care system that pays for value and aligns with our desire to reinforce and support patient freedom of choice. We believe that transparency in pricing can empower consumers of health care services to make more informed decisions about their care and lower the rate of growth in health care costs. Health care consumers today lack meaningful and timely access to pricing information that could, if available, help them choose a lower-cost setting or a higher-value provider. Patients are often unaware of site-of-care cost differentials until it is too late (*see* Aparna Higgins & German Veselovskiy, *Does the Cite of Care Change the Cost of Care,* Health Affairs (June 2, 2016), *https://www.healthaffairs.org/do/10.1377/hblog20160602.055132/full/*). Multiple surveys and studies have revealed that patients want their health care providers to engage in cost discussions, and one recent national survey found that a majority of physicians want to have cost of care discussions with their patients (*see* Caroline E. Sloan, MD & Peter A. Ubel, MD, *The 7 Habits of Highly Effective Cost-of-Care Conversations,* Annals of Internal Medicine (May 7, 2019), *https://annals.org/aim/issue/937992*, and *Let's Talk About Money,* The University of Utah (2018), *https://uofuhealth.utah.edu/value/lets-talk-about-money.php*). The point of referral presents an ideal opportunity to have such cost-of-care discussions.

In the CMS RFI, we solicited comment on the role of transparency in the context of the physician self-referral law. In particular, we solicited comment on whether, if provided by the referring physician to a beneficiary, transparency about a physician's financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing (such as data about quality of services provided) would reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address. Many commenters replied that making a physician's financial relationships and cost of care information available could be useful. One commenter suggested that providing clear and transparent information was vital in the health care industry where patients are often vulnerable, confused, and unsure of their options. This commenter further opined that informed patients are empowered to take charge of their health care and better assist their providers in fulfilling their health care needs. Several commenters shared similar support for transparency efforts. Another commenter stated that transparency of a physician's financial relationships along with price and quality of care information would be valuable to patients in choosing providers and care pathways. This commenter maintained that these actions would also engage patients in protecting against possible unintended consequences of value-based arrangements. Other commenters raised concerns that information on price transparency and a physician's financial relationships with other health care providers, in combination with already-required disclosures under HIPAA, informed consent information and forms, insurance payment authorization forms, and other paperwork that patients receive or must complete would serve only to inundate patients with paperwork that they will find confusing or simply not read. These commenters contended that, although transparency is an appealing concept, requiring additional disclosures would result in more burden than benefit.

The June 24, 2019 Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First [7] recognizes the importance of price transparency. The Executive Order directs Federal agencies to take historic steps toward getting patients the information they need and when they need it to make well-informed decisions about their health care. CMS has already acted on the Executive Order in two ways. First, by finalizing price transparency requirements in the CY 2020 OPPS final rule (84 FR 65524) to improve the availability of meaningful pricing information to the public by requiring hospitals to make public a machine-readable file that contains a hospital's gross charges and payer-specific negotiated charges, plus discounted cash prices, the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge for all items and services provided by the hospital beginning January 1, 2021. Second, through the Transparency in Coverage final rule (85 FR 72158), HHS, along with the Departments of Labor and Treasury, finalized requirements for

[7] Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First, June 24, 2019, available at: *https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/*.

health insurance issuers and plans in the individual and group markets to make health care prices and expected out-of-pocket costs for enrollees available to the general public to help facilitate more informed health care purchasing decisions with the goal of driving down health care costs. We continue to believe that all consumers need price and quality information in advance to make an informed decision when they choose a good or service, including at the point of a referral for such goods or services. As we stated in the proposed rule, by making meaningful price and quality information more broadly available, we can protect patients and increase competition, innovation, and value in the health care system (84 FR 55788).

We remain committed to ensuring that physician self-referral law policies do not infringe on patient choice and the ability of physicians and patients to make health care decisions that are in the patient's best interest. We continue to believe that it is important for patients to have timely access to information about all aspects of their care, including information about the factors that may affect the cost of services for which they are referred. As stated in the proposed rule, a patient who is made aware, for example, that costs may differ based on the site of service where the referred services are furnished, may become a more conscious consumer of health care services (84 FR 55788). Access to such information may also spark important conversations between patients and their physicians, promoting patient choice and the ability of physicians and patients to make health care decisions that are in the patient's best interest. In conjunction with their physicians' determination of the need for recommended health care services and the urgency of that need, information on the factors that may affect the cost of such services could ensure that patients have the information they need to shop and seek out high-quality care at the lowest possible cost.

It remains CMS' goal to establish policies that facilitate consumers' ability to participate actively and meaningfully in decisions relating to their care. At the same time, we continue to be cognizant that including requirements regarding price transparency in the exceptions to the physician self-referral law raises certain challenges for the regulated industry. In the proposed rule, we sought comments on how to pursue our price transparency objectives in the context of the physician self-referral law, both in the context of a value-based health care system and otherwise, and how to overcome the technical, operational, legal, cultural, and other challenges to including price transparency requirements in the physician self-referral regulations (84 FR 55788). Specifically, we requested comments regarding the availability of pricing information and out-of-pocket costs to patients (including information specific to a particular patient's insurance, such as the satisfaction of the patient's applicable deductible, copayment, and coinsurance obligations); the appropriate timing for the dissemination of information (that is, whether the information should be provided at the time of the referral, the time the service is scheduled, or some other time); and the burden associated with compliance with a requirement in an exception to the physician self-referral law to provide information about the factors that may affect the cost of services for which a patient is referred. Finally, we sought comment regarding whether the inclusion of a price transparency requirement in a value-based exception would provide additional protections against program or patient abuse through the active participation of patients in selecting their health care providers and suppliers.

In furtherance of our goal of price transparency for all patients, we solicited comments regarding whether to consider a requirement related to price transparency in every exception for value-based arrangements at § 411.357(aa) (84 FR 55789). While we did not propose regulatory changes, we considered whether to require that a physician provide a notice or have a policy regarding the provision of a public notice that alerts patients that their out-of-pocket costs for items and services for which they are referred by the physician may vary based on the site where the services are furnished and based on the type of insurance that they have. Because of limits on currently available pricing data, we continue to believe that such a requirement could be an important first step in breaking down barriers to cost-of-care discussions that play a beneficial role in a value-based health care system. We further explained the public notice provided or reflected in the policy could be made in any form or manner that is accessible to patients. For example, a notice on the physician's website, a poster on the wall in the physician's office, or a notice in a patient portal used by the physician's patients would all be acceptable. We stated our expectation that any notice would be written in plain language that would be understood by the general public. We refer readers to the Plain Writing Act of 2010 (Pub. L. 111–274, enacted on October 13, 2010) for further information. We sought comment on whether, if we finalize such a requirement, it would be helpful for CMS to provide a sample notice and, if we provide a sample notice, whether we should deem such a notice to satisfy the requirement described. We stated that we would not require public notice in advance of referrals for emergency hospital services to avoid delays in urgently needed care. We solicited comment on other options for price transparency requirements in the value-based exceptions to the physician self-referral law, as well as whether we should consider for a future rulemaking the inclusion of price transparency requirements in exceptions to the physician self-referral law included in our existing regulations.

We received several comments from both consumers of health care and entities that provide health care services. Nearly all the commenters were united in their support that patients should have access to clear, accurate, and actionable cost-sharing information and recognized the important role price transparency has in patient care. However, many supportive commenters also asserted that requiring price transparency disclosures as a requirement of an exception to the physician self-referral law is not an appropriate mechanism for promoting price transparency objectives given the strict liability nature of the law. We continue to believe that health care markets work more efficiently and provide consumers with higher-value health care if we promote policies that encourage choice and competition. We thank the commenters for their thoughtful responses, which will help inform future agency policy making on this important objective. We are not finalizing any price transparency provisions in this rulemaking.

B. Fundamental Terminology and Requirements

1. Background

As described in the proposed rule and in greater detail in this section of the final rule, many of the statutory and regulatory exceptions to the physician self-referral law include one, two, or all the following requirements: The compensation arrangement itself is commercially reasonable; the amount of the compensation is fair market value; and the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals (or, in some

cases, other business generated between the parties). These requirements are presented in various ways within the statutory and regulatory exceptions, but it is clear that they are separate and distinct requirements, each of which must be satisfied when included in an exception. As we stated in the proposed rule, the regulated industry and its complementary parts, such as the health care valuation community, have sought additional guidance from CMS regarding whether compliance with one of the requirements is dependent on compliance with one or both of the others (84 FR 55789). In addition, these and other stakeholders have requested clarification on our policy with respect to when an arrangement is considered commercially reasonable, under what circumstances compensation is considered to take into account the volume or value of referrals or other business generated between the parties, and how to determine the fair market value of compensation. According to stakeholders and commenters on the proposed rule, False Claims Act (31 U.S.C. 3729 through 3733) case law has exacerbated the challenge of complying with these three fundamental requirements. Endeavoring to establish bright-line, objective regulations for each of these fundamental requirements, we proposed a new definition of ''commercially reasonable'' at § 411.351, proposed to establish special rules that identify the universe of circumstances under which compensation would be considered to take into account the volume or value of a physician's referrals or the other business generated by a physician for the entity paying the compensation, and proposed to revise the definitions of ''fair market value'' and ''general market value'' in our regulations at § 411.351. Our overall intention with these policies is to reduce the burden of compliance with the physician self-referral law, provide clarification where possible, and achieve the goals of the Regulatory Sprint. As we stated in the proposed rule, we believe that clear, bright-line rules would enhance both stakeholder compliance efforts and our enforcement capability. We believe that the policies finalized here will provide the clarity that will benefit the regulated industry, CMS, and our law enforcement partners (84 FR 55789).

In developing our proposals for guidance on the fundamental terminology and requirements, we considered three basic questions—

- Does the arrangement make sense as a means to accomplish the parties' goals?
- How did the parties calculate the remuneration?
- Did the calculation result in compensation that is fair market value for the asset, item, service, or rental property?

These questions relate, respectively, to the definition of commercial reasonableness, the volume or value standard and the other business generated standard, and the definition of fair market value. In this section of the final rule, we provide detailed descriptions of our final definitions and special rules. Importantly, our final policies relate only to the application of section 1877 of the Act and our physician self-referral regulations. Although other laws and regulations, including the anti-kickback statute and CMP law, may utilize the same or similar terminology, the policies finalized in this final rule do not affect or in any way bind OIG's (or any other governmental agency's) interpretation or ability to interpret such terms for purposes of laws or regulations other than the physician self-referral law. In addition, our interpretation of these key terms does not relate to and in no way binds the Internal Revenue Service with respect to its rulings and interpretation of the Internal Revenue Code or State agencies with respect to any State law or regulation that may utilize the same or similar terminology. We note further that, to the extent terminology is the same as or similar to terminology used in the Quality Payment Program within the PFS, our final policies do not affect or apply to the Quality Payment Program.

We received the following general comment on our discussion of the three key requirements in the exceptions to the physician self-referral law, and our response follows. We respond to comments specific to each of the key requirements in sections II.B.2. through II.B.4. of this final rule.

Comment: Several commenters requested that CMS' articulation of the ''big three'' requirements should be preserved in the final rule. Specifically, commenters described as ''cornerstones'' of exceptions to the physician self-referral law the requirements that: (1) The compensation arrangement is commercially reasonable; (2) the compensation is not determined in any manner that takes into account the volume or value of a physician's referrals (the volume or value standard) or the other business generated by a physician for the entity (the other business generated standard); and (3) the amount of compensation is fair market value for the items or services furnished under the arrangement. Commenters strongly agreed with our statements that these requirements are separate and distinct and should be disentangled from each other.

Response: We agree with the commenters that it is important to reiterate that the statutory and regulatory requirements regarding compensation arrangements that are commercially reasonable, compensation that is not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by a physician, and compensation that is fair market value for items or services actually furnished are separate and distinct requirements, each of which must be satisfied when included in an exception to the physician self-referral law.

2. Commercially Reasonable (§ 411.351)

In the proposed rule, we proposed to include at § 411.351 a definition for the term ''commercially reasonable.'' As described previously, many of the statutory and regulatory exceptions to the physician self-referral law include a requirement that the compensation arrangement is commercially reasonable. For example, the exception at section 1877(e)(2) of the Act for *bona fide* employment relationships requires that the remuneration provided to the physician is pursuant to an arrangement that would be commercially reasonable (even if no referrals were made to the employer). The exception at section 1877(e)(3)(A) of the Act for personal service arrangements uses slightly different language to describe this general concept, and requires that the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. The exception at § 411.357(y) for timeshare arrangements, which the Secretary established in regulation using his authority at section 1877(b)(4) of the Act, requires that the arrangement would be commercially reasonable even if no referrals were made between the parties. Despite the prevalence of this requirement (in one form or another), as we stated in the proposed rule (84 FR 55790), we addressed the concept of commercial reasonableness only once—in our 1998 proposed rule—where we stated that we are interpreting ''commercially reasonable'' to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals (63 FR 1700). Until now, the physician self-referral regulations themselves lacked a codified

definition for the term commercially reasonable.

As discussed previously in this section II.B.2., the key question to ask when determining whether an arrangement is commercially reasonable is simply whether the arrangement makes sense as a means to accomplish the parties' goals. The determination of commercial reasonableness is not one of valuation. We continue to believe that this determination should be made from the perspective of the particular parties involved in the arrangement. In addition, the determination that an arrangement is commercially reasonable does not turn on whether the arrangement is profitable; compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable. In the proposed rule, we described numerous examples of compensation arrangements that commenters on the CMS RFI asserted would be commercially reasonable, despite the fact that the party paying the remuneration does not recognize an equivalent or greater financial benefit from the items or services purchased in the transaction, or that the party receiving the remuneration incurs costs in furnishing the items or services that are greater than the amount of the remuneration received. We acknowledge that, even knowing in advance that an arrangement may result in losses to one or more parties, it may be reasonable, if not necessary, to nevertheless enter into the arrangement. Examples of reasons why parties would enter into such transactions include community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of quality and health outcomes.

To provide the certainty requested by stakeholders, we proposed to codify in regulation the definition of ''commercially reasonable'' at § 411.351. We proposed two alternative definitions for the term. First, we proposed to define ''commercially reasonable'' to mean that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. In the alternative, we proposed to define ''commercially reasonable'' to mean that the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty. We sought comment on each of these definitions as well as input from stakeholders regarding other possible definitions that would provide clear guidance to enable parties to structure their arrangements in a manner that ensures compliance with the requirement that their particular arrangement is commercially reasonable. We also proposed to clarify in regulation text that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties (84 FR 55790). After considering the comments on the definition of ''commercially reasonable,'' we are finalizing in our regulation at § 411.351 that commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. The final regulation also states that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Finally, many of the exceptions to the physician self-referral law require that an arrangement is commercially reasonable ''even if no referrals were made between the parties'' or ''even if no referrals were made to the employer.'' The exceptions use varying phrasing to describe this requirement and we do not repeat each iteration here. Although we did not include this language in the final definition of ''commercially reasonable,'' it remains an important constraint when determining whether an arrangement satisfies the requirements of an applicable exception. As described elsewhere in this final rule, we have revised the exception for fair market value compensation to include this important constraint in the requirement at § 411.357(l)(4) that a compensation arrangement is commercially reasonable. In addition, we included this requirement in the new exception for limited remuneration to a physician that we are finalizing at § 411.357(z).

We received the following comments and our responses follow.

Comment: Most commenters supported our proposal to define the term ''commercially reasonable'' in regulation, stating a preference for one of the two alternative definitions that we proposed. A few commenters offered alternative definitions of ''commercially reasonable,'' such as an arrangement that is ''appropriately designed to meet the parties' legitimate business goals from the perspective of the parties to the arrangement'' and an arrangement that is ''entered into for a legitimate business interest and is reasonably structured to achieve the legitimate business interest.'' A small number of commenters urged us not to finalize the proposed definition so that parties could rely on CMS' statements in the 1998 proposed rule, noting that it has been workable for industry stakeholders for many years.

Several commenters requested that, if we finalize the first alternative proposed definition, we strike the limitation that the arrangement is on similar terms and conditions as like arrangements. These commenters asserted that parties to an arrangement would not have access to data to identify ''like arrangements'' or be aware of their terms and conditions. In addition, parties may enter into a novel compensation arrangement that bears minimal, if any, resemblance to existing arrangements against which it could be compared for ''similar terms.'' The commenters also highlighted the burden associated with obtaining third party opinions in order to satisfy this requirement. Other commenters preferred the second alternative definition because of its focus on the comparison to other similarly situated providers, suppliers, and physicians, although one of these commenters noted that the requirement that an arrangement makes ''commercial sense'' could exclude arrangements for noncommercial purposes, such as meeting community needs. A few other commenters suggested combining the two proposed definitions in order to emphasize that the determination of commercial reasonableness should be from the perspective of, and further a legitimate business need of, the particular parties to the arrangement, and also that the arrangement should be compared to arrangements with similarly situated parties. One of these commenters also suggested that the definition of ''commercially reasonable'' should reflect the importance of evaluating the market conditions relevant to the arrangement. A few other commenters offered that CMS should finalize a policy under which an arrangement would be commercially reasonable if it meets either of the proposed alternative definitions. Another commenter urged CMS to ensure that the definition of ''commercially reasonable'' does not shelter abusive arrangements.

Response: We agree that a definition requiring a compensation arrangement to be on similar terms as like arrangements in order to be commercially reasonable does not provide for the clarity that we and stakeholders seek and, in fact, could increase the burden on parties that must seek the expertise of outside

organizations to ensure compliance with the requirement that their arrangement is commercially reasonable. We are finalizing a modified definition of ''commercially reasonable'' to address commenters' concerns. In line with the suggestion of some commenters, the final definition of ''commercially reasonable'' incorporates aspects of each of the proposed alternative definitions. Under the definition finalized at § 411.351, commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. We believe that the definition of ''commercially reasonable'' at final § 411.351 is consistent with the guidance we provided in the 1998 proposed rule, appropriately considers the characteristics of the parties to the actual arrangement being assessed for its commercial reasonableness, and will adequately ensure that parties cannot protect abusive arrangements under the guise of ''commercial reasonableness.''

Comment: One commenter asked us to confirm that the test of commercial reasonableness relates primarily to the non-financial elements of an arrangement.

Response: We understand the commenter to be inquiring whether the existence of the compensation arrangement must be commercially reasonable as opposed to whether the precise compensation terms of the arrangement must be commercially reasonable. That is, we understand the commenter to be seeking confirmation that the concept of commercial reasonableness does not relate to the amount of or formula for compensation paid under an arrangement, but rather whether the entire arrangement is commercially reasonable. As we stated in the proposed rule and previously in this final rule, when determining the commercial reasonableness of an arrangement, the question to ask is whether the arrangement makes sense as a means to accomplish the parties' goals. The test is not whether the compensation terms alone make sense as a means to accomplish the parties' goals; however, the compensation terms of an arrangement are an integral part of the arrangement and impact its ability to accomplish the parties' goals (84 FR 55790).

Comment: One commenter urged us to adopt a policy under which an arrangement would be presumed to be commercially reasonable if, contemporaneously with the commencement of the arrangement, the governing body of the entity (or its designee) documents in writing that the arrangement furthers the legitimate business purpose of the parties. Another commenter urged us to adopt an irrebuttable presumption that, if the purpose of an arrangement is documented and achieved, the commercial reasonableness of the arrangement cannot be contradicted by extrinsic evidence. The commenter asserted that, in the absence of such a presumption, entities are left susceptible to the potential for False Claims Act litigation predicated on an unsupported inference of ill intent on behalf of the contracting parties.

Response: We do not believe that merely documenting in writing that an arrangement furthers a legitimate business purpose of the parties is sufficient to ensure that the arrangement is commercially reasonable, even if the identified purpose is achieved. Moreover, our final definition of ''commercially reasonable'' requires more than furtherance of a legitimate business purpose of the parties. The arrangement must also be sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. If the only requirement to demonstrate that an arrangement is commercially reasonable is contemporaneous written documentation stating that it is commercially reasonable, unscrupulous parties could satisfy the requirement simply by including sufficient template language in their documentation, even if, in reality, the arrangement could not further the legitimate business purposes of the parties (assuming they have a legitimate business need for the arrangement) or is not sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. Further, the fact that an arrangement ultimately achieved a legitimate business purpose of the parties does not necessarily mean that it was a commercially reasonable arrangement. Where a financial relationship exists between a physician (or an immediate family member of a physician) and an entity to which the physician makes referrals for designated health services, compliance with the physician self-referral law requires substantive compliance, not merely documentary (or ''paper'') compliance, with the requirements of an applicable exception. An irrebuttable presumption of commercial reasonableness that ensures that parties are shielded from allegations of violation of the False Claims Act if their documentation includes specific language or their arrangement ultimately achieved its intended purpose would pose a risk of program or patient abuse.

Comment: A few commenters requested that we include in regulation text a non-exhaustive list of legitimate business purposes for purposes of applying the definition of ''commercially reasonable.'' One commenter specifically referenced our discussion in the proposed rule of examples of compensation arrangements that CMS RFI commenters believed would be commercially reasonable even if they did not result in profit for one or more of the parties.

Response: As we stated in the proposed rule, we find compelling the comments of commenters on the CMS RFI regarding the types of arrangements they believed would be commercially reasonable even if they did not result in profit for one or more of the parties (84 FR 55790). However, these types of arrangements do not depict the entire universe of arrangements that could be commercially reasonable. We decline to provide examples in regulation text of arrangements that may be commercially reasonable, because the determination of whether a compensation arrangement is commercially reasonable is dependent on the facts and circumstances of the parties. Even a non-exhaustive list of the types of arrangements that are potentially commercially reasonable could inadvertently limit or otherwise proscribe the types of arrangements that parties undertake. Moreover, it is not possible to know definitively that, in every instance, a particular type of arrangement would be commercially reasonable. An arrangement that is commercially reasonable for one set of parties may not be commercially reasonable for another.

Comment: One commenter that asked us to provide examples of arrangements that would be considered commercially reasonable asserted that examples are necessary so that parties may avoid unintentional noncompliance with the commercial reasonableness requirement, particularly in the context of value-based arrangements for which the commercial reasonableness of the arrangement is required. Another commenter stated its assumption that CMS ''expects that value-based payments must still be tested for commercial reasonableness'' and asked us to confirm its belief. The commenter specifically requested us to confirm that, for any new exceptions for value-based arrangements, the determination of commercial reasonableness may be based on more than just cost savings to the value-based enterprise. The commenter asserted that, in

arrangements where cost savings are negligible, enhanced access to care, increased care coordination, and improved quality of care may support a determination of the value-based arrangement's commercial reasonableness.

Response: As we explained in section II.A.2. of this final rule, the new exceptions for value-based arrangements finalized at § 411.357(aa) do not include a requirement that the value-based arrangement is commercially reasonable. Of course, parties may utilize any applicable exception to demonstrate compliance with the physician self-referral law. If the exception upon which parties to a value-based arrangement rely includes a requirement that the arrangement is commercially reasonable, the arrangement must further a legitimate business purpose of the parties. In addition, it must be sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. However, as we stated in the proposed rule, the determination of whether the arrangement is commercially reasonable is not one of valuation (84 FR 55790), and an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Comment: A few commenters expressed concern that the term ''legitimate business purpose'' does not provide enough certainty for stakeholders. Another commenter asked how the requirement that an arrangement must further a legitimate business purpose of the parties in order to be commercially reasonable is different from a query into the subjective intent of the parties (that is, whether a purpose of the arrangement is to induce or reward referrals).

Response: The term ''legitimate business purpose'' appears in both the statutory and regulatory exceptions to the physician self-referral law. The commenter did not clearly explain how the use of this term in the definition of ''commercially reasonable'' is any less clear or appropriate than its use in the special rule at § 411.354(d)(4)(v) or the exceptions for the rental of office space at § 411.357(a)(3), the rental of equipment at § 411.357(b)(2), personal service arrangements at § 411.357(d)(1)(iii), and fair market value compensation at § 411.357(l)(4) (prior to its revision in this final rule). Given that the language finalized in our definition of ''commercially reasonable'' is identical to that used in longstanding statutory and regulatory exceptions and our special rule at § 411.354(d)(4)(v), we see no reason why stakeholders would be suddenly unable to ascertain the meaning of the term. We see great benefit in using consistent terminology throughout our regulations where we intend an identical policy or standard. With respect to the second commenter's question, we believe that the requirement represents an objective standard. This requirement in the definition of ''commercially reasonable'' is similar to the requirements in the exceptions referenced, all of which represent objective standards. Although identifying the business purpose of an arrangement may entail an inquiry into the parties' intent for the arrangement, the requirement in the definition of ''commercially reasonable'' that the arrangement furthers a legitimate business purpose of the parties would be considered only after the determination that there actually exists a legitimate business purpose for the arrangement. As we stated in the proposed rule, conduct that violates a criminal law, such as inducing or rewarding referrals in violation of the anti-kickback statute, would not be a legitimate business purpose for an arrangement (84 FR 55791). Thus, the arrangement would not be commercially reasonable, and the question of whether the arrangement *furthers* a legitimate business purpose would not be reached.

Comment: One commenter agreed that an arrangement does not further the legitimate business purposes of the parties if, for example, a hospital engages more medical directors than it needs to furnish required medical direction, but asked for additional guidance on our interpretation of the term ''legitimate business purpose.'' Another commenter expressed concern that unscrupulous parties could identify the goal of attracting a physician's business as a ''legitimate business purpose'' of its compensation arrangement with the physician. This commenter also suggested that an arrangement that is unprofitable should have discrete and well-documented factors establishing that it furthers a legitimate business purpose of the parties (such as a regulatory or licensure requirement or a patient access issue) in order to qualify as commercially reasonable.

Response: As we noted in the proposed rule, arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements (84 FR 55790). For example, a hospital may enter into an arrangement for the personal services of a physician to oversee its oncology department. If the hospital needs only one medical director for the oncology department, but later enters into a second arrangement with another physician for oversight of the department, the second arrangement merely duplicates the already-obtained medical directorship services and may not be commercially reasonable. Although the evaluation of compliance with the physician self-referral law always requires a review of the facts and circumstances of the financial relationship between the parties, the commercial reasonableness of multiple arrangements for the same services is questionable.

In the proposed rule, we discussed numerous examples of compensation arrangements described by CMS RFI commenters as commercially reasonable, in their opinions, despite the fact that the party paying the remuneration does not recognize an equivalent or greater financial benefit from the items or services purchased in the transaction, or that the party receiving the remuneration incurs costs in furnishing the items or services that are greater than the amount of the remuneration received (84 FR 55790). The underlying purposes of the compensation arrangements described by the CMS RFI commenters included addressing community need, timely access to health care services, fulfillment of licensure or regulatory obligations (including those under the Emergency Medical Treatment and Labor Act (EMTALA)), the provision of charity care, and the improvement of quality and health outcomes. We believe that all of these purposes could qualify as ''legitimate business purposes'' of the parties to an arrangement, depending on the facts and circumstances of the parties.

We share the second commenter's concern that unscrupulous parties could claim that a compensation arrangement is commercially reasonable by claiming that attracting a physician's business is a ''legitimate business purpose'' for their arrangement. In the proposed rule, we explained that we were not proposing to include the phrase ''even if no referrals were made'' in the definition of ''commercially reasonable'' because this qualifying phrase (or similar language) appears in the regulation text of many exceptions that require an arrangement to be commercially reasonable (84 FR 55791). Thus, it would be redundant to include the language in the definition of ''commercially reasonable'' itself. We were clear that we were not proposing to remove this qualifying language from the exceptions in which it appears. We believe that this qualifying language provides critical protection against

program or patient abuse, as an arrangement must be commercially reasonable even if no referrals were made by the physician. As described in greater detail in sections II.D.10. and II.E.1. of this final rule, we are adding this language where it had not previously been included in the exception for fair market value compensation at § 411.357(l) and in the new exception for limited remuneration to a physician finalized at § 411.357(z). An arrangement whose purpose is to attract a physician's business, even if the parties claim this purpose, would not be commercially reasonable in the absence of the physician's referrals and, thus, would not satisfy this important requirement of the exceptions generally applicable to compensation arrangements that call for items or services to be provided by a physician.

Finally, in the proposed rule, we also discussed our review of Internal Revenue Service (IRS) Revenue Ruling 97–21 and its conclusion that a hospital may not engage in substantial unlawful activities and maintain its tax-exempt status because the conduct of an unlawful activity is inconsistent with charitable purposes (84 FR 55790). In this final rule, we are similarly taking the position that an activity that is in violation of a criminal law would not be a legitimate business purpose of the parties and, therefore, would not be commercially reasonable for purposes of the physician self-referral law. We note that the absence of a criminal violation would not, in and of itself, establish that an arrangement is commercially reasonable.

Comment: Several commenters addressed our preamble discussion regarding the requirement in our regulations that a compensation arrangement must be commercially reasonable even if no referrals were made between the parties. One commenter suggested that, if CMS intends that an arrangement should be commercially reasonable even in the absence of referrals, that phrase should be added to the exceptions or, if referrals may be considered, CMS should so state. These commenters requested that we expressly confirm that the term ''referral'' in these references in our exceptions has the meaning set forth in § 411.351 of our regulations. Another commenter asserted that the ''even if no referrals were made'' requirement is an integral part of commercial reasonableness in applying the physician self-referral law. This commenter suggested that we add this limiting phrase to § 411.357(l)(4).

Response: We agree with the commenters regarding the inclusion of the language ''even if no referrals were made between the parties'' and, for the reasons explained in our response to the previous comment, have added this language to the exception for fair market value compensation at § 411.357(l) and the new exception for limited remuneration to a physician at § 411.357(z). Unless the context indicates otherwise, the term ''referral'' has the meaning set forth in § 411.351 throughout the physician self-referral regulations, including in this limiting phrase.

Comment: Most commenters that addressed the definition of ''commercially reasonable'' expressed appreciation for the clarification in the proposed rule of our position that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable (84 FR 55790), and supported the inclusion of this policy statement at proposed § 411.351. Commenters echoed the potential reasons set forth in the proposed rule why an arrangement may not be profitable, but yet still commercially reasonable, and added that, despite the parties' prediction of profitability at the onset of an arrangement, an arrangement may simply not ''pan out.'' Many of these commenters requested that we extend our policy regarding the effect that the profitability of a compensation arrangement has on the arrangement's ability to satisfy the requirement that it is commercially reasonable to state that commercial reasonableness is unrelated, wholly unrelated, or irrelevant to the profitability of the arrangement to one or more of the parties. One commenter suggested that we state in regulation text that profitability is not a requirement for an arrangement to be commercially reasonable. Another commenter expressed concern that the use of the word ''may'' does not provide a bright-line rule for stakeholders. One commenter noted that the concept of commercial reasonableness has been used as an enforcement tool for business decisions that might not have turned out to be good business decisions, but were made in good faith, or that are strategic in nature without making absolute ''commercial sense.'' In contrast, a few commenters asserted that there are circumstances under which it would not be commercially reasonable for parties to enter into an arrangement that they know would result in substantial losses to one or more of the parties. One commenter, while agreeing that the issue of commercial reasonableness is not solely determined by physician practice profitability, stated that physician practice losses may indicate arrangements that should be further scrutinized as possible fraud and abuse risks.

Response: We decline to adopt the commenters' suggestions regarding the extension of our policy. Although we believe that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable, we are not convinced that the profitability of an arrangement is completely irrelevant or always unrelated to a determination of its commercial reasonableness, for instance, in a case where the parties enter into an arrangement aware of its certain unprofitability and there exists no identifiable need or justification—other than to capture the physician's referrals—for the arrangement.

We agree with the commenters that it is appropriate and helpful to include in regulation text our policy regarding the impact of an arrangement's profitability on its ability to satisfy the requirement that it is commercially reasonable. We are not adopting the alternative characterization of our policy as ''profitability is not a requirement for an arrangement to be commercially reasonable'' because we do not believe that this language is as clear or precise as the language we proposed. We are finalizing in regulation text at § 411.351 our policy that ''an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.''

Comment: One commenter asked for confirmation that any definition of ''commercially reasonable'' finalized by CMS will not apply to regulations enforced by the IRS, OIG or pursuant to state law.

Response: The commenter is correct. The introductory language to § 411.351 where the definition of ''commercially reasonable'' appears in our regulation text states that the definitions in [Title 42, part 411, Subpart J] apply only for purposes of section 1877 of the Act and [Subpart J].

Comment: One commenter asked how CMS interprets the requirements at § 411.357(a)(3) and (b)(2) in the exceptions for the rental of office space and equipment, respectively, that the leased office space or equipment does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement. The commenter noted that this requirement *and* a requirement that the compensation arrangement is commercially reasonable are included in each of these statutory (and regulatory) exceptions. The commenter expressed confusion about our

description in the proposed rule of the requirement in the statutory exception for personal service arrangements that the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement as another form of the requirement that an arrangement is commercially reasonable (84 FR 55790).

Response: We believe that the requirement that the leased office space or equipment does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement is intended to prevent sham lease arrangements under which a lessee pays remuneration to the lessor under the guise of rental charges where the rental charges are for office space or equipment for which the lessee has no genuine or reasonable use. The statutory and regulatory exceptions for the rental of office space and the rental of equipment also include a requirement that the lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor. The new definition of ''commercially reasonable'' at final § 411.351 applies for purposes of interpreting this requirement. Thus, the particular lease arrangement must further a legitimate business purpose of the parties to the arrangement and must be sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.

The statutory exception at section 1877(e)(3)(A) of the Act for personal service arrangements includes a requirement that the aggregate services contracted for under the personal service arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. We included this requirement in the regulatory exception for personal service arrangements at § 411.357(d)(1)(iii). Unlike the exceptions for the rental of office space and the rental of equipment, the exception for personal service arrangements does not include—either in the statute or our regulations—a separate requirement that the arrangement is commercially reasonable. The commenter raises a valid point regarding our statement in the proposed rule that, with respect to the exception for personal services, the ''does not exceed what is reasonable and necessary'' requirement is a different form of the requirement that the arrangement is commercially reasonable. Upon further review of the similarities and differences in the requirements in the statutory and regulatory exceptions for the rental of office space, the rental of equipment, and personal service arrangements, we are retracting our statement from the proposed rule that the requirement at section 1877(e)(3)(A) of the Act (incorporated at § 411.357(d)(1)(iii)) equates to a requirement that the personal service arrangement is commercially reasonable.

As we stated in this section II.B.2., with respect to lease arrangements for office space and equipment, we interpret the ''does not exceed what is reasonable and necessary'' requirement as a protection against sham lease arrangements under which a lessee pays remuneration to the lessor under the guise of rental charges where the rental charges are for office space or equipment for which the lessee has no genuine or reasonable use. We similarly interpret this requirement in the context of the exception for personal service arrangements as a protection against sham arrangements for the services of a physician for which the entity has no genuine or reasonable use. In the proposed rule, we stated that arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements (84 FR 55790). We provided the example of a hospital that enters into multiple arrangements for medical director services for a single department even though the hospital needs only one medical director for the department. We stated that the commercial reasonableness of multiple arrangements for the same services is questionable. Multiple arrangements for the same personal services may also result in the failure of the duplicate arrangements to satisfy the ''reasonable and necessary'' requirement in the exception for personal services at section 1877(e)(3)(A) of the Act and § 411.357(d)(1)(iii). In the proposed rule, we also discussed our view that an activity that is in violation of criminal law would not be a legitimate business purpose of the parties and, therefore, would not be commercially reasonable for purposes of the physician self-referral law (84 FR 55791). Activity that is in violation of criminal law would also fail to satisfy the requirement in the exception for personal service arrangements that the services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law. Thus, although the exception for personal service arrangements does not include a requirement that the arrangement is commercially reasonable, the other requirements in the exception guard against program or patient abuse in an important and essentially equivalent way.

We note that the exception for personal service arrangements at § 411.357(d)(1) includes a requirement that the arrangement covers all the services to be furnished by the physician (or an immediate family member of the physician) to the entity. The exception permits the use of a master list of contracts that is maintained and updated centrally and available for review by the Secretary upon request. In addition, a personal service arrangement must have a duration of at least 1 year in order to qualify for protection under the exception at § 411.357(d)(1). We are aware that, because personal service arrangements may not satisfy these requirements, parties often rely on the exception at § 411.357(l) for fair market value compensation to protect their arrangements for the personal services of physicians and their immediate family members. We remind readers that the exception for fair market value compensation includes a requirement that the arrangement is commercially reasonable, and as explained in section II.D.10. of this final rule, we are revising the regulation text of that exception to require that the arrangement is commercially reasonable even if no referrals were made between the parties.

3. The Volume or Value Standard and the Other Business Generated Standard (§ 411.354(d)(5) and (6))

Many of the exceptions at section 1877(e) of the Act (''Exceptions Relating to Other Compensation Arrangements'') and in our regulations include a requirement that the compensation paid under the arrangement is not determined in any manner that takes into account the volume or value of referrals by the physician who is a party to the arrangement, and some exceptions also include a requirement that the compensation is not determined in any manner that takes into account other business generated between the parties. We refer to these as the ''volume or value standard'' and the ''other business generated standard,'' respectively. Throughout the regulatory history of the physician self-referral law, we have shared our interpretation of these standards and responded to comments as they arose. Despite our attempt at establishing clear guidance regarding the application of the volume or value standard and the other business generated standard, commenters to several requests for information,

including the CMS RFI, identified their lack of a clear understanding as to whether compensation will be considered to take into account the volume or value of referrals or other business generated by the physician as one of the greatest risks they face when structuring arrangements between entities furnishing designated health services and the physicians who refer to them. They stated that, not only do they face the risk of penalties under the physician self-referral law, but, because a violation of the physician self-referral law may be the predicate for liability under the False Claims Act, entities are susceptible to both government and whistleblower actions that can result in significant penalties through litigation or settlement. In the proposed rule, we proposed regulations intended to provide objective tests for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician. We also provided a brief history of the guidance to date on the volume or value standard and the other business generated standard. We believe it is useful to repeat that history in this final rule.

In the 1998 proposed rule, we discussed the volume or value standard as it pertains to the criteria that a physician practice must meet to qualify as a ''group practice'' (63 FR 1690). We also stated that we would apply this interpretation of the volume or value standard throughout our regulations (63 FR 1699 through 1700). In the discussion of group practices, we stated that we believe that the volume or value standard precludes a group practice from paying physician members for each referral they personally make or based on the volume or value of the referred services (63 FR 1690). We went on to state that the most straightforward way for a physician practice to demonstrate that it is meeting the requirements for group practices would be for the practice to avoid a link between physician compensation and the volume or value of any referrals, regardless of whether the referrals involve Medicare or Medicaid patients (63 FR 1690). However, because our definition of ''referral'' at § 411.351 includes only referrals for designated health services, we also noted that a physician practice could compensate its members on the basis of non-Medicare and non-Medicaid referrals, but would be required to separately account for revenues and distributions related to referrals for designated health services for Medicare and Medicaid patients (63 FR 1690). (See section II.C. of this final rule for a discussion of the historical inclusion of Medicaid referrals in our regulations and our revisions to the group practice rules.) Outside of the group practice context, these principles apply generally to compensation from an entity to a physician. We also addressed the other business generated standard in the 1998 proposed rule, stating that we believe that the Congress may not have wished to except arrangements that include additional compensation for other business dealings and that, if a party's compensation contains payment for other business generated between the parties, we would expect the parties to separately determine if this extra payment falls within one of the exceptions (63 FR 1700).

In Phase I, we finalized our policy regarding the volume or value standard and the other business generated standard, responding to comments on the proposals included in the 1998 proposed rule. Most importantly, we revised the scope of the volume or value standard to permit time-based or unit of service-based compensation formulas (66 FR 876). We also stated that the phrase ''does not take into account other business generated between the parties'' means that the fixed, fair market value payment cannot take into account, or vary with, referrals of designated health services payable by Medicare or Medicaid or any other business generated by the referring physician, including other Federal and private pay business (66 FR 877), noting that the phrase ''generated between the parties'' means business generated *by the referring physician* for purposes of the physician self-referral law (66 FR 876). We stated that section 1877 of the Act establishes a straightforward test that compensation should be at fair market value for the work or service performed or the equipment or [office] space leased—not inflated to compensate for the physician's ability to generate other revenue (66 FR 877). Finally, in response to a comment about whether the compensation paid to a physician for the purchase of his or her practice could include the value of the physician's referrals of designated health services to the practice, we stated that compensation may include the value of designated health services made by the physician to his or her practice if the designated health services referred by the selling physician satisfied the requirements of an applicable exception, such as the in-office ancillary services exception, and the purchase arrangement is not contingent on future referrals (66 FR 877). This policy would apply also to the value of the physician's referrals of designated health services to his or her practice if the compensation arrangement between the physician and the practice satisfied the requirements of an applicable exception.

Also in Phase I, we established special rules on compensation at § 411.354(d)(2) and (3) that deem unit-based compensation not to take into account the volume or value of referrals or other business generated between the parties if certain conditions are met (66 FR 876 through 877). These rules state that unit-based compensation will be deemed not to take into account the volume or value of referrals if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of designated health services. Unit-based compensation will be deemed not to take into account the volume or value of other business generated between the parties to a compensation arrangement if the compensation is fair market value for items or services actually provided and does not vary during the term of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business. We note that the special rules use the phrase ''takes into account referrals'' (or other business generated) rather than ''takes into account *the volume or value of* referrals'' (or other business generated). Both special rules apply to time-based or per-unit of service-based (''per-click'') compensation formulas. However, as we later noted in Phase II, the special rules on unit-based compensation are intended to be safe harbors, and there may be some situations not described in § 411.354(d)(2) or (3) where an arrangement does not take into account the volume or value of referrals or other business generated between the parties (69 FR 16070).

In Phase II, we clarified that personally performed services are not considered other business generated by the referring physician (69 FR 16068). We also stated that fixed compensation (that is, one lump-sum payment or several individual payments aggregated together) can take into account or otherwise reflect the volume or value of referrals (for example, if the payment exceeds the fair market value for the items or services provided) (69 FR 16059). We noted that a determination whether the compensation does, in fact, take into account or otherwise reflect the volume or value of referrals will

require a case-by-case examination based on the facts and circumstances. (We note that the language ''otherwise reflects'' was determined to be superfluous and removed from our regulation text in Phase III (72 FR 51027).)

Until now, we had not codified regulations defining the volume or value standard or the other business generated standard, although the special rule at § 411.354(d)(4) sets forth the circumstances under which a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier without running afoul of the volume or value standard. For the reasons explained in more detail below and in our responses to comments, in this final rule, we are finalizing special rules at § 411.354(d)(5) and (6) that supersede our previous guidance, including guidance with which they may be (or appear to be) inconsistent. Our final policies relate to the volume or value and other business generated standards as they apply to the definition of remuneration at section 1877(h)(1)(C) of the Act and § 411.351 of our regulations, the exception for academic medical centers at § 411.355(e)(1)(ii), and various exceptions for compensation arrangements in section 1877(e) of the Act and § 411.357 of our regulations, including the new exception established in this final rule for limited remuneration to a physician at § 411.357(z). In addition, the regulation at final § 411.354(d)(5)(i) applies for purposes of section 1877(h)(4) of the Act and the group practice regulations at § 411.352(g) and (i). The final policies do not apply for purposes of applying the exceptions at § 411.357(m), (s), (u), (v), and (w), or for purposes of applying the new exception finalized in this final rule at § 411.357(bb) for cybersecurity items and services. We are including regulation text at § 411.354(d)(5)(iv) and (6)(iv) regarding the application of the volume or value standard and the other business generated standard for purposes of applying these exceptions. Given the revisions to our regulations at § 411.354(c)(2) and (d)(1), which eliminate language regarding compensation that is determined in any manner that takes into account the volume or value of referrals or other business generated by a physician, the final special rules at § 411.354(d)(5) and (6) do not apply for purposes of determining the existence of an indirect compensation arrangement under § 411.354(c)(2) or applying the special rule on compensation that is deemed to be set in advance at § 411.354(d)(1). For the reasons discussed below in response to comments, the final special rules at § 411.354(d)(5) and (6) do not apply for purposes of applying the special rules for unit-based compensation at § 411.354(d)(2) and (3). We are including regulation text at § 411.354(d)(5)(iv) and (6)(iv) regarding the application of the volume or value standard and the other business generated standard for purposes of applying the special rules for unit-based compensation.

As we stated in the proposed rule, we believe there is great value in having an objective test for determining whether the compensation is determined in any manner that takes into account the volume or value of referrals or takes into account other business generated between the parties (84 FR 55793). Our final rules establish such a test. We are finalizing an approach that, rather than deeming compensation under certain circumstances not to have been determined in a manner that takes into account the volume or value of referrals or takes into account other business generated between the parties, defines exactly when compensation will be considered to take into account the volume or value of referrals or take into account other business generated between the parties. Under our final regulations, which we believe create the bright-line rule sought by commenters and other stakeholders, outside of the circumstances at § 411.354(d)(5) and (6), compensation will not be considered to take into account the volume or value of referrals or take into account other business generated between the parties, respectively. In other words, only when the mathematical formula used to calculate the amount of the compensation includes referrals or other business generated as a variable, and the amount of the compensation correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity, is the compensation considered to take into account the volume or value of referrals or take into account the volume or value of other business generated. We believe that our final regulations are consistent with the position we articulated in Phase I where we stated that, in general, we believe that a compensation structure does not directly take into account the volume or value of referrals if there is no direct correlation between the total amount of a physician's compensation and the volume or value of the physician's referrals of designated health services (66 FR 908).

In the proposed rule, we explained that, even with nonsubstantive changes to standardize (where possible) the language used to describe the volume or value standard and the other business generated standard in our regulations, due to the varying language used throughout the statutory and regulatory schemes, we find it impossible to establish a single *definition* for the volume or value and other business generated standards (84 FR 55793). Therefore, instead of a definition at § 411.351, we proposed special rules for compensation arrangements that would apply regardless of the exact language used to describe the standards in the statute and our regulations. We also explained that, because section 1877 of the Act defines a compensation arrangement as any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity, we believe that it is necessary that the tests address circumstances where the compensation is from the entity to the physician, as well as where the compensation is from the physician to the entity. Therefore, we proposed two separate special rules for the volume or value standard and two separate special rules for the other business generated standard.

Under our proposals, compensation from an entity to a physician (or immediate family member of the physician) would take into account the volume or value of referrals only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that *positively correlates* with the number or value of the physician's referrals to the entity. For example, if the physician (or immediate family member) *receives additional compensation* as the number or value of the physician's referrals to the entity increase, the physician's (or immediate family member's) compensation would positively correlate with the number or value of the physician's referrals. In the proposed rule, we stated that, unless the special rule at § 411.354(d)(2) for unit-based compensation applies and its conditions are met, the physician's (or immediate family member's) compensation would take into account the volume or value of referrals (84 FR 55793). For the reasons explained in our response to comments below, we are retracting this statement. Under the

policies set forth in this final rule, as described in our response to comments below, the special rules at § 411.354(d)(2) and (3) are not applicable to compensation that takes into account the volume or value of referrals under final § 411.354(d)(5)(i) or (6)(i) or to compensation that takes into account other business generated by a physician under final § 411.354(d)(5)(ii) or (6)(ii). We have revised the regulation text at § 411.354(d)(2) and (3) accordingly. If compensation takes into account the volume or value of referrals or the volume or value of other business generated under final § 411.354(d)(5) or (6), that determination is final. The special rules at § 411.354(d)(2) and (3) may not be applied to then deem the compensation not to take into account the volume or value of referrals or other business generated.

To illustrate our proposed policy, in the proposed rule, we provided an example under which a physician organization does not qualify as a group practice under § 411.352 of the physician self-referral regulations. Under the example, the physician organization pays its physicians a percentage of collections attributed to the physician, including personally performed services and services furnished by the physician organization (the physician's ''pool''). If a physician's pool includes amounts collected for designated health services furnished by the physician organization that he ordered but did not personally perform, the physician's compensation takes into account the volume or value of his referrals to the physician organization. Assuming the physician is paid 50 percent of the amount in his pool, the mathematical formula that illustrates the physician's compensation would be: Compensation = (.50 × collections from personally performed services) + (.50 × collections from referred designated health services) + (.50 × collections from non-designated health services referrals). The policy proposed with respect to when compensation from an entity to a physician (or immediate family member of the physician) takes into account other business generated would operate in the same manner (84 FR 55793).

Analogously, we proposed that compensation from a physician (or immediate family member of the physician) to an entity takes into account the volume or value of referrals only if the formula used to calculate the compensation paid by the physician includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the compensation that *negatively correlates* with the number or value of the physician's referrals to the entity. For example, if a physician (or immediate family member) *pays less compensation* as the number or value of the physician's referrals to the entity increases, the compensation from the physician to the entity would negatively correlate with the number or value of the physician's referrals. In the proposed rule, we stated that, unless the special rule at § 411.354(d)(2) for unit-based compensation applies and its requirements are met (which seems unlikely), the compensation would take into account the volume or value of referrals (84 FR 55793). We are retracting this statement. Under the policies set forth in this final rule, as described above and in our response to comments below, the special rules at § 411.354(d)(2) and (3) are not applicable to compensation that takes into account the volume or value of referrals under final § 411.354(d)(5)(i) or (6)(i) or to compensation that takes into account the volume or value of other business generated by the physician under final § 411.354(d)(5)(ii) or (6)(ii). If compensation takes into account the volume or value of referrals or the volume or value of other business generated under final § 411.354(d)(5) or (6), that determination is final. The special rules at § 411.354(d)(2) and (3) may not be applied to then deem the compensation not to take into account the volume or value of referrals or other business generated.

To illustrate our proposed policy, in the proposed rule, we provided an example under which a physician leases medical office space from a hospital. Our example assumed that the rental charges are $5,000 per month and the arrangement provides that the monthly rental charges will be reduced by $5 for each diagnostic test ordered by the physician and furnished in one of the hospital's outpatient departments. Under our proposal, the compensation (that is, the rental charges) would take into account the volume or value of the physician's referrals to the hospital. The mathematical formula that illustrates the rental charges paid by the physician to the hospital would be: Compensation = $5,000 − ($5 × the number of designated health services referrals). The proposed policy with respect to when compensation from a physician (or immediate family member of the physician) to an entity takes into account other business generated would operate in the same manner (84 FR 55793 through 55794).

We are finalizing our proposals with modifications to the structure of the regulations. The final regulations are designated at § 411.354(d)(5)(i), (ii), and (iii) (with respect to compensation from an entity to a physician (or immediate family member of a physician)) and § 411.354(d)(6)(i), (ii), and (iii) (with respect to compensation from a physician (or immediate family member of a physician) to an entity). As set forth at final § 411.354(d)(5)(iv) and (6)(iv), these special rules do not apply for purposes of applying the exceptions at § 411.357(m), (s), (u), (v), and (w), or for purposes of applying the new exception established in this final rule at § 411.357(bb) for cybersecurity items and services. Although our final regulations are ''special rules'' on compensation, we interpret them in the same manner as definitions. That is, the special rules are intended to define the universe of circumstances under which compensation is considered to take into account the volume or value of referrals or other business generated by the physician. If the methodology used to determine the physician's compensation or the payment from the physician does not fall squarely within the defined circumstances, the compensation is not considered to take into account the volume or value of the physician's referrals or other business generated by the physician, as appropriate, for purposes of the physician self-referral law.

We also proposed additional policies at proposed § 411.354(d)(5)(i)(B) and (ii)(B), and at proposed § 411.354(d)(6)(i)(B) and (ii)(B), outlining narrowly-defined circumstances under which fixed-rate compensation (for example, a fixed annual salary or an unvarying per-unit rate of compensation) would be considered to be determined in a manner that takes into account the volume or value of referrals or other business generated by a physician for the entity paying the compensation. For the reasons described in response to comments below and in section II.B.4. of this final rule, we are not finalizing the proposed regulations. However, to address the concerns prompting the policy described in the proposed rule with respect to referrals of designated health services, we are revising § 411.354(d)(4), which sets forth requirements that must be met if a physician's compensation is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; that is, if, under the *bona fide* employment relationship, personal service arrangement, or managed care contract the physician's referrals are directed to a particular provider, practitioner, or supplier. The final

policy is designated at § 411.354(d)(4)(vi) and states that, regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician, neither the existence of the compensation arrangement nor the amount of the compensation may be contingent on the volume or value of the physician's referrals to the particular provider, practitioner, or supplier. See section II.B.4. of this final rule for further discussion of § 411.354(d)(4)(vi).

In the proposed rule, we stated that we believe that the modifier ''directly or indirectly'' is implicit in the requirements that compensation is not determined in *any* manner that takes into account the volume or value of referrals or the volume or value of other business generated (84 FR 55794). We are finalizing our proposal to remove the modifier from the regulations where it appears in connection with the standards and the related requirements. We also highlighted that, where the statute or regulations specifically allow parties to determine compensation in a manner that only indirectly takes into account the volume or value of referrals (for example, in the exception for EHR items and services at § 411.357(w)(6) and the rules for a group practice's distribution of profit shares and payment of productivity bonuses at section 1877(h)(4)(B) of the Act and § 411.352(i)), our regulations include guidance regarding direct versus indirect manners of determining compensation. We solicited comment on the need for additional guidance or regulation text that includes deeming provisions related to the volume or value standard in these exceptions. Based on the comments we received, we are not revising our regulations to provide further guidance on the deeming provisions (except as provided in section II.D.11. of this final rule with respect to the deeming provision in the exception at § 411.357(w) for EHR items and services).

Finally, in the proposed rule, we discussed related guidance in our Phase II regulation (69 FR 16088 through 16089). In Phase II, a commenter presented a scenario under which a hospital employs a physician at an outpatient clinic and pays the physician for each patient seen at the clinic; the physician reassigns his or her right to payment to the hospital, and the hospital bills for the Part B physician service (with a site-of-service reduction); and the hospital also bills for the hospital outpatient services, which may include some procedures furnished as ''incident to'' services in a hospital setting. The Phase II commenter's concern was that the payment to the physician is inevitably linked to a facility fee, which is a designated health service (that is, a hospital service). Accordingly, the commenter wondered whether the payment to the physician would be considered an improper productivity bonus based on a referral of designated health services (that is, the facility fee). In response, we stated that the fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement). We acknowledged stakeholder concerns that, following the July 2, 2015 opinion of the United States Court of Appeals for the Fourth Circuit in *United States ex rel. Drakeford* v. *Tuomey Healthcare System, Inc.* (792 F.3d 364) (*Tuomey*), CMS may no longer endorse this policy. We stated that we believe that the objective tests for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated may address these concerns; however, for clarity, we reaffirmed the position we took in the Phase II regulation. We stated that, with respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service. We also clarified that our guidance extends to compensation arrangements that do not rely on the exception for *bona fide* employment relationships at § 411.357(c), and under which a physician is paid using a unit-based compensation formula for his or her personally performed services, provided that the compensation meets the conditions in the special rule at § 411.354(d)(2). That is, under a personal service arrangement, an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula—even when the entity bills for designated health services that correspond to such personally performed services—and the compensation will not take into account the volume or value of the physician's referrals if the compensation meets the conditions in the special rule at § 411.354(d)(2) (*see* 69 FR 16067). This is true whether the compensation arrangement is analyzed under an exception applicable to compensation arrangements directly between an entity and a physician or is an indirect compensation arrangement analyzed under the exception at § 411.357(p). Our position has not changed since the publication of Phase II, and we reaffirm here our statements in the proposed rule. An association between personally performed physician services and designated health services furnished by an entity does not convert compensation tied solely to the physician's personal productivity into compensation that takes into account the volume or value of a physician's referrals to the entity or the volume or value of other business generated by the physician for the entity. Although commenters requested that we codify these policies in regulation text, we decline to do so, as we do not believe that it is necessary given the policies set forth in the final regulations at § 411.354(d)(5) and (6). However, as described below in our response to comments, we are revising the regulations at § 411.354(c)(2) regarding the existence (that is, definition) of an indirect compensation arrangement. We believe the revisions to § 411.354(c)(2) may alleviate the commenters' concerns.

We received the following comments and our responses follow.

Comment: Most commenters supported the proposed special rules on the volume or value standard and the other business generated standard. Some commenters requested modification of the standards, as described in other comments below. The commenters in support of our proposed special rules generally appreciated the clarification of terms that they asserted have been a source of confusion among providers, physicians, *qui tam* relators, and courts. The commenters stated that the objective tests established in the proposed special rules are easily understood, which, in turn, will greatly ease the burden on providers and suppliers attempting to ensure compliance with the volume or value and other business generated standards, as well as make a clear path for law enforcement and the regulated industry. Commenters urged CMS to finalize objective standards for this critical terminology. In contrast, one commenter asserted that the proposed special rules do not adequately explain what is meant by ''includes the physician's referrals to the entity as a variable'' and would create significantly more confusion than the current standard. This commenter asserted that this lack of clarity could allow for abusive compensation arrangements and hamper enforcement efforts.

Response: We are finalizing most of our proposals to establish objective tests for whether compensation takes into account the volume or value of a physician's referrals to an entity or the volume or value of other business generated by a physician for an entity. We agree with the commenters that our final policies will establish a clear path for parties to design compensation arrangements that comply with the volume or value standard and other business generated standard found in many of the exceptions to the physician self-referral law. In turn, the objective standards should assist in law enforcement efforts by making it clear whether compensation paid to or from a physician takes into account the volume or value of a physician's referrals to an entity or the volume or value of other business generated by a physician for an entity. As discussed more fully in our response to other comments, we are also clarifying in regulation text that, if compensation takes into account the volume or value of a physician's referrals to an entity or the volume or value of other business generated by a physician for an entity under final § 411.354(d)(5) or (6), no special rule, including those at § 411.354(d)(2) and (3), may be applied to reverse that determination.

We disagree with the commenter that asserted that the proposed special rules would create significantly more confusion related to the volume or value standard and the other business generated standard, and note that nearly all other commenters that addressed these specific proposals asserted that the proposed special rules would provide clarity for parties seeking to ensure that compensation is not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by a physician. With respect to the meaning of ''includes the physician's referrals to the entity as a variable'' as included in the regulation text at final § 411.354(d)(5)(i) and (6)(i), we refer readers to the examples provided in the proposed rule and restated above that illustrate the mathematical formulas for determining compensation that takes into account the volume or value of a physician's referrals. The term ''variable'' has the meaning it does with respect to general mathematical principles—a symbol for a number we do not yet know. Thus, if an entity pays a physician one-fifth of a bonus pool that includes all collections from a set of services furnished by an entity, including those from designated health services referred by a physician to the entity, the formula used to calculate the physician's compensation is: (.20 × the value of the physician's referrals of designated health services) + (.20 × the value of the other business generated by the physician for the entity) + (.20 × the value of services furnished by the entity that were not referred or generated by the physician). The value of the physician's referrals to the entity is a variable in this formula, as is the value of the other business generated by the physician.

Comment: A small number of commenters did not support our proposals for special rules that identify the universe of compensation formulas that take into account the volume or value of a physician's referrals or the other business generated by the physician for an entity. One of the commenters asserted that the standards were too narrow to protect the Medicare program from abuse, noting that, under our proposals, a hospital could make payment to a physician in anticipation of future referrals without a mathematical formula explicitly delineating it. Other commenters opposed CMS finalizing any of its proposals, while not specifically opposing the proposed special rules for the volume or value and other business generated standards.

Response: Although we agree with the commenters regarding the importance of program integrity, we believe that the certainty afforded by the objective standards we are finalizing is critical to reduce the burden associated with compliance with the physician self-referral law's volume or value and other business generated standards. We believe that the policies finalized at § 411.354(d)(5) and (6), coupled with the new condition at § 411.354(d)(4)(vi) prohibiting an entity from making the existence of a compensation arrangement or the amount of the compensation contingent on the volume or value of the physician's referrals to the particular provider, practitioner, or supplier (as well as the other requirements of our exceptions) mitigates the potential for program or patient abuse asserted by the commenters. We remind parties that arrangements that involve remuneration from an entity to a physician (or vice versa) implicate the anti-kickback statute. An arrangement under which a hospital makes a payment to a physician in anticipation of future referrals would be suspect under the anti-kickback statute. Moreover, our revised definition of ''referral'' at § 411.351 clarifies that referrals are not items or services to be protected under the exceptions to the physician self-referral law, regardless of whether or not it is possible to ascribe a fair market value to them.

Comment: A large number of commenters requested that CMS specifically address personal productivity compensation by finalizing in regulation text the interpretations we described in the proposed rule (84 FR 55795). Some commenters requested that CMS confirm that personal productivity compensation is permissible in all settings. Others requested that we revise the exceptions for personal service arrangements, fair market value compensation, and indirect compensation arrangements to expressly permit compensation formulas based on a physician's personal productivity. All of the commenters noted that productivity pay for personally performed services is among the most prevalent compensation methodologies used by hospitals and other entities to compensate surgeons and other proceduralists, as well as physicians who do not attend to patients in a hospital setting. Commenters stated that, despite our affirmative statements in the proposed rule that, under a personal service arrangement, an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula even when the entity bills for designated health services that correspond to such personally performed services, and the compensation will not take into account the volume or value of the physician's referrals if the compensation meets the conditions of the special rule at § 411.354(d)(2) (84 FR 55795), they remain concerned that an entity may still have to defend its compensation practices in the event of a False Claims Act allegation because satisfaction of all the requirements of an applicable exception to the physician self-referral law is an affirmative defense.

Response: We decline to revise the text of the regulations as requested by the commenters. We reaffirm our statements in the proposed rule, including those with respect to productivity-based compensation under a *bona fide* employment relationship. We also confirm that our policy applies to indirect compensation arrangements. To be clear, under a *bona fide* employment relationship, personal service arrangement, or indirect compensation arrangement, a physician may be compensated for his or her personally performed services using a unit-based compensation formula—even when the entity with which the physician has a direct or indirect compensation arrangement bills for designated health services that

correspond to such personally performed services—and the compensation will not take into account the volume or value of the physician's referrals if the unit-based compensation meets the conditions of the special rule at § 411.354(d)(2). Similarly, under a personal service arrangement or indirect compensation arrangement, a physician may be compensated for his or her personally performed services using a unit-based compensation formula—even when the entity with which the physician has a direct or indirect compensation arrangement bills for other business that correspond to such personally performed services—and the compensation will not take into account other business generated by the physician if the unit-based compensation meets the conditions of the special rule at § 411.354(d)(3).

We note that the policies described in the proposed rule (84 FR 55795) and in this response regarding the application of the special rules for unit-based compensation have been superseded by the policies finalized in this final rule. However, these policies would be applied when analyzing compensation arrangements for compliance with the physician self-referral law during periods prior to the effective date of this final rule. They have never applied and will continue not to apply for purposes of analyzing ownership or investment interests for compliance with the physician self-referral law, as none of our exceptions in § 411.356 include a requirement identical or analogous to the volume or value standard or other business generated standard. To reiterate, neither the special rules at § 411.354(d)(2) and (3) nor any guidance regarding our interpretation of the volume or value standard or other business generated standard are relevant for purposes of applying the exceptions at § 411.356(c)(1) and (3), both of which incorporate the requirements of § 411.362, including the requirement at § 411.362(b)(3)(ii)(B) that a hospital must not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

Comment: A significant number of commenters requested that we clarify that the positions CMS took in prior litigation, including *Tuomey,* and the discussion in the proposed rule regarding productivity-based compensation were based on its then-current policy, not on the policies finalized here. Commenters asserted that this is necessary to avoid confusing the special rules on the volume or value standard and other business generated standard that we are finalizing in this final rule—under which productivity compensation would not trigger the volume or value standard of the exceptions for *bona fide* employment relationships, personal service arrangements, or fair market value compensation—with *Tuomey's* ''correlation theory.'' The commenters also asserted that, under the policies finalized here, there would no longer be a need for the productivity bonus ''safe harbor'' at § 411.357(c)(4).

Response: Productivity compensation based *solely* on a physician's personally performed services does not take into account the volume or value of the physician's referrals or other business generated by a physician under the policies finalized in this final rule. Such compensation would satisfy the volume or value standard and the other business generated standard, where it appears, in the exceptions for *bona fide* employment relationships, personal service arrangements, and fair market value compensation, all of which apply to direct compensation arrangements between entities and physicians. Although the productivity bonus ''safe harbor'' at § 411.357(c)(4) would not be necessary to protect productivity compensation based solely on a physician's personally performed services under this final rule, the provision is included in section 1877(e)(2) of the Act and, therefore, we are not removing it from our regulations. *Prior to this final rule,* productivity compensation based solely on a physician's personally performed services would not take into account the volume or value of a physician's referrals if the conditions of the special rule at § 411.354(d)(2) were met. Thus, even prior to this final rule, the productivity bonus ''safe harbor'' at § 411.357(c)(4) would not have been necessary to ensure that a physician's referrals to his or her employer did not violate the physician self-referral law due to the fact that the physician received productivity compensation from the employer based solely on the physician's personally performed services. As we stated in the proposed rule and repeated above, the special rules at § 411.354(d)(5) and (6), as finalized, supersede our previous guidance, including guidance with which they may be (or appear to be) inconsistent (84 FR 55792). The policies finalized here are prospective only and represent CMS policy regarding the volume or value standard and the other business generated standard going forward from the effective date of this final rule.

Comment: Two commenters asked us to confirm whether a ''tiered'' compensation model would take into account the volume or value of a physician's referrals. The commenters both presented the following example: For the first 50 procedures that a physician performs at a hospital, the physician is paid $X per procedure. For the next 25 procedures that the physician performs at the hospital, the physician is paid $X + $20. The commenters did not specify whether the physician made the referrals for the corresponding designated health services furnished by the hospital.

Response: The commenters did not provide sufficient facts to enable us to respond to their request. Parties may use the process set forth in our regulations at §§ 411.370 through 411.389 to request an advisory opinion on whether a specific referral or referrals relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act.

Comment: One commenter expressed support for the approach of identifying the universe of circumstances in which compensation will be considered to take into account the volume or value of referrals or other business generated, rather than the current approach that identifies limited circumstances in which compensation is deemed to not take into account the volume or value of a physician's referrals or other business generated by the physician for an entity. The commenter asserted that the regulatory certainty provided under our approach will allow hospitals to encourage physicians to improve quality, reduce cost, and provide leadership by permitting quality and outcomes-based bonuses payable to physicians, bonuses to physician leaders based on system success, and unit-based compensation based on personally performed services that sometimes, but not always, result in referrals of designated health services. Another commenter asked whether incentive compensation paid only in the event of the hospital's achievement of overall financial performance goals would take into account the volume or value of a particular physician's compensation. The commenter gave the example of a physician receiving a 15 percent bonus if the system has a 2 percent margin, and a 20 percent bonus if the system has a 4 percent margin.

Response: We agree that identifying for stakeholders the universe of circumstances in which we believe compensation is determined in a

manner that takes into account the volume or value of a physician's referrals or other business generated by the physician is preferable to our former policy, which articulated a general rule that compensation may not be determined in any manner that takes into account the volume or value of referrals (or other business generated by a physician) and provided a single ''safe harbor'' for assurance that the specific compensation does not violate the general rule. We caution that outcomes-based bonuses, as described by the commenter, could fall within the circumstances of the special rules at final § 411.354(d)(5) and (6), depending on how they are structured and whether referrals to the entity or other business generated by the physician for the entity are variables anywhere in the mathematical formula for determining the compensation. Although bonus compensation based on ''system success'' may not include referrals to or other business generated for the entity as a variable in many instances, the determination of whether the formula to determine the compensation includes such variables must be made on a case-by-case basis. As we explain above and in our response to other comments, unit-based compensation based solely on personally performed services would not include the physician's referrals to or the other business generated by the physician for the entity as a variable and, regardless of whether an entity furnishes designated health services in conjunction with the physician's personally performed services, would not take into account the volume or value of the physician's referrals or other business generated by the physician.

Comment: Many commenters noted that our proposed interpretations of the volume or value and other business generated standards do not readily translate in the context of nonmonetary compensation such as the donation of EHR items and services or medical staff incidental benefits. These commenters requested that we not apply the special rules at § 411.354(d)(5) and (6) to the exceptions where the remuneration to or from a physician generally is not calculated as a mathematical formula.

Response: We agree with the commenters in part. The final special rules at § 411.354(d)(5) and (6) do not apply for purposes of applying the exceptions for medical staff incidental benefits at § 411.357(m), professional courtesy at § 411.357(s), community-wide health information systems at § 411.357(u), electronic prescribing items and services at § 411.357(v), electronic health records items and services at § 411.357(w), and cybersecurity technology and related services at new § 411.357(bb). These exceptions have ''volume or value'' requirements that are somewhat unique and the special rules are not a perfect fit. We have included language at final § 411.354(d)(5)(iv) and (6)(iv) to indicate the inapplicability of the special rules for purposes of applying these particular exceptions to the physician self-referral law. However, the requirement in the exception for nonmonetary compensation at § 411.357(k)(1)(i), which requires that the nonmonetary compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician, is similar to those in the exceptions where cash remuneration may be provided and the special rules at final § 411.354(d)(5) and (6) can be easily applied.

Comment: A few commenters requested that CMS confirm that the proposed special rules at § 411.354(d)(5) and (6) would apply to the determination of whether an indirect compensation arrangement exists. Another commenter requested confirmation that the special rules set forth at final § 411.354(d)(5) and (6) would apply to the determination of whether a physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals (§ 411.352(g)) and the requirements under the special rules for profit shares and productivity bonuses at § 411.352(i).

Response: Except as specified in § 411.354(d)(5)(iv) and (6)(iv), the proposed special rules interpreting the volume or value standard at § 411.354(d)(5)(i) and (6)(i) apply in all instances where our regulations require an analysis of whether compensation is determined in any manner that takes into account the volume or value of a physician's referrals. Likewise, except as specified in § 411.354(d)(5)(iv) and (6)(iv), the proposed special rules interpreting the other business generated standard at § 411.354(d)(5)(ii) and (6)(ii) apply in all instances where our regulations require an analysis of whether compensation is determined in any manner that takes into account the volume or value of other business generated by a physician. Given the revisions to the regulations at § 411.354(c)(2) finalized in this final rule, and because the special rules at final § 411.354(d)(5) and (6) have only prospective application, the special rules at § 411.354(d)(5) and (6) do not apply to the determination of whether an indirect compensation arrangement exists under § 411.354(c)(2). For the reasons explained in the response to a comment below, the special rules at final § 411.354(d)(5) and (6) do not apply for purposes of applying the special rules on unit-based compensation at § 411.354(d)(2) and (3). As described in section II.C.1. of this final rule, the terms ''based on'' and ''related to'' exist in the regulation text at § 411.352(g) and (i). We interpret these terms to equate to ''takes into account'' when referring to the volume or value of referrals. Thus, the special rule at final § 411.354(d)(5)(i) applies for purposes of interpreting and applying the group practice regulations at § 411.352(g) and (i), which apply only to compensation from the group practice to the physician and the physician's referrals (but do not apply to the other business generated by the physician for the group practice).

Comment: Citing concerns related to recent False Claims Act litigation, many commenters asked CMS to refrain from using the term ''correlation'' in the final regulations. Commenters suggested that we use the term ''causal relationship'' in lieu of ''correlation'' in the special rules. The commenters were concerned that the term ''correlation'' could create an inference that compensation could violate the volume or value or other business generated standards without a causal relationship between referrals or other business generated and the compensation to or from the physician.

Response: We have provided definitions for ''positive correlation'' and ''negative correlation'' to indicate specifically what mathematical formulas will be problematic under the final rules. We believe that our regulations, as finalized, are clear and express the agency's interpretation of the volume or value standard and the other business generated standard.

Comment: A few commenters requested that CMS require that the physician's referrals are a written or otherwise expressly articulated variable in the formula for calculating the compensation paid to a physician. The commenters asserted that, under the proposed special rule, it is not clear how the formula would be assessed, and recommended language would signify that, for purposes of applying § 411.357(d)(5), the test is not one of subjective intent. The commenters made the same request, for the same reasons, with respect to the other business generated standard. Another commenter suggested that we require that the compensation formula has a ''direct and explicit'' variable that results in an increase or decrease in the physician's

compensation that ''directly, explicitly and'' positively (or negatively) correlates with the number of value of the physician's referrals to (or other business generated for) the entity in order to take into account the volume or value of referrals (or other business generated).

Response: We decline to adopt the commenter's suggestions. We believe that the special rules finalized at § 411.354(d)(5) and (6) sufficiently articulate objective tests for assessing whether compensation takes into account the volume or value of a physician's referrals or the other business generated by a physician for an entity. We disagree that the final special rules lack clarity or imply that the volume or value standard and other business generated standard are subjective tests. Compensation paid *to a physician* takes into account the volume or value of referrals if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity, regardless of whether the formula is written in a particular place or manner. The same applies to compensation that takes into account other business generated by the physician for the entity making the payment to the physician.

Comment: A large number of commenters requested that we not finalize our proposal to consider fixed-rate compensation for which there is a predetermined, direct correlation to the physician's prior referrals to the entity or the other business previously generated by the physician for the entity to take into account the volume or value of referrals or other business generated by the physician. Noting that fixed rate compensation (for example, $200,000 per year) qualifies as unit-based compensation, some commenters asserted that, even if we were to finalize this proposal, once the special rules for unit-based compensation at § 411.354(d)(2) and (3) are applied, fixed-rate compensation that fails the proposed test(s) would nonetheless be deemed not to take into account the volume or value of referrals or other business generated under the existing regulations at § 411.354(d)(2) and (3). Other commenters stated that the proposal regarding fixed-rate compensation would not establish the objective rule we sought and would continue the uncertainty that the industry currently faces.

Response: We agree with the commenters that the special rules for unit-based compensation at § 411.354(d)(2) and (3) essentially nullify the proposed special rule regarding fixed-rate compensation that takes into account the volume or value of a physician's referrals or other business generated by the physician for an entity. We are not finalizing our proposals for additional special rules outlining the circumstances under which we would consider fixed-rate compensation to be determined in a manner that takes into account the volume or value of referrals or other business generated by a physician for the entity paying the compensation.

In the proposed rule, we stated that merely hoping for or even anticipating future referrals or other business is not enough to show that compensation is determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the entity; however, we also stated that we are concerned with an ''if X, then Y'' correlation between compensation in the current term and prior referrals or previous other business generated by a physician (84 FR 55794). Our proposed policy focused on fixed-rate compensation under a current arrangement where there is a predetermined, direct correlation between the volume or value of a physician's prior referrals or the other business previously generated for the entity and the rate of compensation paid to or by the physician (or immediate family member of the physician). We provided examples of objectionable tiered compensation structures that condition a physician's compensation on the volume or value of his or her referrals to an entity. The conditioning of the existence of a compensation arrangement would also fall within such a structure; for example, ''if the value of the physician's referrals does not equal $1,000,000 in the prior period, the physician's employment arrangement will be terminated and his compensation from the entity will equal $0.'' We believe that there is a risk of program or patient abuse when a physician will receive no future compensation if he or she fails to refer as required. The same is true if the amount of the physician's compensation conditioned on the volume or value of a physician's referrals to an entity (or another provider, practitioner, or supplier). Therefore, in lieu of the proposed policies treating ''if X, then Y'' compensation methodologies as potential concerns under the volume or value standard and other business generated standard, we are revising the special rule at § 411.354(d)(4) to address our concerns when a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier (including the entity providing the compensation to the physician)—in other words, when the physician's referrals are directed to a particular provider, practitioner, or supplier. Under the policy at final § 411.354(d)(4)(vi), regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as set forth at paragraph (d)(5) of this section, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the volume or value of the physician's referrals to the particular provider, practitioner, or supplier. We discuss this revision in more detail in section II.B.4. of this final rule.

Comment: A few commenters requested clarification of the examples in the proposed rule regarding fixed-rate tiered compensation set using a predetermined, ''if X, then Y'' methodology. One commenter suggested that our statement in the proposed rule that the tiered compensation methodology in the example provided (84 FR 55794) is at odds with our confirmation that a productivity bonus will not take into account the volume or value of referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service.

Response: The example of tiered compensation referenced by the commenter related to our proposal regarding fixed-rate compensation. We are not finalizing our proposal to consider fixed-rate compensation to take into account the volume or value of referrals or other business generated by a physician. Therefore, it is unnecessary to further address the examples as requested by the commenters *in the context of the volume or value standard.* We note that the regulation at final § 411.354(d)(4)(vi) regarding making the existence of a compensation arrangement or the amount of a physician's compensation contingent on the volume or value of a physician's referrals to a particular provider, practitioner, or supplier may apply to the commenter's examples. See section II.B.4. of this final rule for a further discussion of final § 411.354(d)(4)(vi).

Comment: A few commenters asserted that the existing special rules at § 411.354(d)(2) and (3) regarding per-unit compensation create confusion when considered in light of the new special rules interpreting the volume or value standard and other business generated standard. Some of the commenters suggested that CMS should remove the regulations at § 411.354(d)(2) and (3), because they would no longer be necessary if we finalize our proposals at § 411.354(d)(5) and (6). The commenters suggested revisions to § 411.354(d)(2) and (3) in the event CMS does not finalize the proposals for special rules at interpreting the volume or value standard and other business generated standard § 411.354(d)(5) and (6). One commenter described a hypothetical arrangement under which a hospital contracts with a surgeon for professional services, the surgeon performs surgeries at the hospital, and the hospital pays the surgeon a fixed amount per personally-performed relative value unit (RVU) that is consistent with the fair market value of the physician's services. Assuming that the compensation would be viewed as not taking into account the volume or value of the physician's referrals to the hospital or other business generated by the physician for the hospital, the commenter asked whether this is the case based on the application of the special rules at final § 411.354(d)(5) and (6) or whether it is because the unit-based compensation satisfies the requirements of the special rules for per-unit compensation at § 411.354(d)(2) and (3). The commenter then questioned whether the special rules for unit-based compensation at § 411.354(d)(2) and (3) would continue to be necessary if we finalize our proposals.

Response: We agree with the commenters that, under the policies finalized here, there is effectively no longer a need for the ''unit-based deeming provision'' at § 411.354(d)(2). The same is true for the deeming provision at § 411.354(d)(3). Unit-based compensation that does not include a physician's referrals to the entity as a variable in the formula used to calculate the physician's (or immediate family member's) compensation would not take into account the volume or value of the physician's referrals and, therefore, there would be no need to apply the special rule at § 411.354(d)(2). Similarly, unit-based compensation that does not include other business generated by a physician for the entity as a variable in the formula used to calculate the physician's (or immediate family member's) compensation would not take into account the volume or value of other business generated and, therefore, there would be no need to apply the special rule at § 411.354(d)(3). If the formula used to calculate a physician's (or immediate family member's) compensation *does* include the physician's referrals to the entity or other business generated by the physician for the entity as a variable (for example, a payment of $50 to the immediate family member of a physician for each patient who receives items or services furnished by the DMEPOS supplier making the payment, including items or service referred by the physician), the compensation would take into account the volume or value of the physician's referrals or other business generated and, under the revisions to § 411.354(d)(2) and (3) finalized here, the special rules for unit-based compensation would not apply.

On and after the effective date of this final rule, the special rules at § 411.354(d)(2) and (3) will be either unnecessary or inapplicable to deem unit-based compensation not to take into account the volume or value of a physician's referrals or other business generated by a physician. However, it is important to preserve the regulations at § 411.354(d)(2) and (3) to assist parties, CMS, and law enforcement in applying the historical policies in effect at the time of the existence of the compensation arrangement being analyzed for compliance with the physician self-referral law. Therefore, we are not removing the regulations at § 411.354(d)(2) and (3) from the physician self-referral regulations, although we are adding language to both § 411.354(d)(2) and (3) to make clear that the regulations may not be applied to deem unit-based compensation *not* to take into account the volume or value of referrals or other business generated by a physician if the compensation formula used to calculate the physician's (or immediate family member's) compensation is determined to take into account the volume or value of referrals or other business generated under final § 411.354(d)(5) or (6). Because the special rules at final § 411.354(d)(5) and (6) have prospective application only, we are confirming in regulation text at § 411.354(d)(5)(iv) and (6)(iv) that they do not apply for purposes of applying the special rules on unit-based compensation at § 411.354(d)(2) and (3), which, as we explained, remain in our regulations only for historical purposes to assist parties, CMS, and law enforcement in applying the historical policies in effect at the time of the existence of the compensation arrangement being analyzed for compliance with the physician self-referral law.

Comment: Several commenters expressed strong support for the proposal to remove the term ''varies with'' from the regulations at § 411.354(c)(2)(ii) and (iii) identifying when an indirect compensation arrangement exists, stating that this would be consistent with CMS' expressed intent for the volume or value standard and other business generated standard to have the same meaning wherever they occur in our regulations. Using the same example from the immediately previous comment, one commenter asked whether, under the regulation at proposed § 411.354(c)(2), the compensation arrangement would constitute an indirect compensation arrangement if the compensation was paid to the physician by an affiliate of the hospital with which the hospital has a financial relationship, forming an unbroken chain of financial relationships between the hospital and the physician. Other commenters questioned whether *any* unbroken chain of financial relationships would create an indirect compensation arrangement if CMS finalizes its proposals to remove the term ''varies with'' from the regulations at § 411.352(c)(2) and establish the special rules interpreting the volume or value standard and other business generated standard at § 411.354(d)(5) and (6).

Response: As we stated in the proposed rule, we proposed nonsubstantive changes to standardize where possible the language used to describe the volume or value standard and the other business generated standard in our regulations (84 FR 55793). Our proposal to remove the term ''varies with'' from the regulation at § 411.354(c)(2) originated with our attempt at standardizing this language. Upon consideration of the comments and after developing our responses, we are not finalizing our proposal to remove the term ''varies with'' from § 411.354(c)(2). If finalized as proposed, the regulatory scheme outlining the conditions under which an indirect compensation arrangement exists would have eliminated most unbroken chains of financial relationships between entities that furnish designated health services and the physicians who refer to them from the scrutiny of the physician self-referral law without affording CMS the opportunity to confirm that the compensation paid to the physician does not pose a risk of the harm section 1877 of the Act is intended to avoid, namely, that the compensation could improperly influence the physician's

medical decision making. We continue to believe in the importance of ensuring that compensation paid to a physician by someone (or some organization) that has a financial relationship with an entity does not improperly influence the physician's medical decision making, resulting in the overutilization of designated health services, patient steering, or other program or patient abuse. However, we believe that the regulatory scheme that casts a wide net to include the vast majority of unbroken chains of financial relationships between an entity and a physician and then weeds out most of those unbroken chains through a showing of compliance with the requirements of the special rules at § 411.354(d)(2) and (3) and the exception at § 411.357(p) is unnecessarily burdensome. The identification of truly problematic physician compensation may be achieved at an earlier stage of analysis. Therefore, we are revising § 411.354(c)(2) to more precisely identify compensation arrangements that may pose a risk of program or patient abuse.

As we stated in Phase I, the existence of a financial relationship between an entity and a physician (or the immediate family member of a physician) is the factual predicate triggering the application of section 1877 of the Act (66 FR 864). (For a similar discussion in Phase II, *see* 69 FR 16057.). Because section 1877 of the Act expressly contemplates that a financial relationship and, specifically, a compensation arrangement, may be directly or indirectly between an entity and a physician (or an immediate family member of a physician), in Phase I, we established a three-part test for determining when an indirect compensation arrangement exists (66 FR 865 through 866). Once all three parts of the test are met, there exists an indirect compensation arrangement that must satisfy the requirements of an applicable exception in order to avoid the referral and billing prohibitions of the physician self-referral law. Also in Phase I, we finalized the exception at § 411.357(p) for indirect compensation arrangements that would apply to unbroken chains of financial relationships that result in indirect compensation arrangements. In Phase I, we explained that some of the statutory and regulatory exceptions operate to exclude certain categories of services from the reach of section 1877 of the Act when certain requirements are satisfied. In effect, services described in those exceptions are not designated health services for purposes of the physician self-referral law (66 FR 867). The service-based exceptions are found in § 411.355 of our regulations. Thus, even if there is an indirect compensation arrangement between an entity and a physician, the service-based exceptions may apply to and protect referrals of the particular services described in the exception. However, referrals for designated health services that do not satisfy the requirements of an applicable service-based exception would be prohibited unless the indirect compensation arrangement satisfies all the requirements of the exception for indirect compensation arrangements at § 411.357(p) (66 FR 867) or, if the entity is a MCO or IPA, the exception at § 411.357(n) for risk-sharing arrangements. (We refer readers to section II.A.2.b.(4). of this final rule for a discussion of the applicability of the exception at § 411.357(n) to indirect compensation arrangements.) In Phase I, we also finalized special rules related to unit-based compensation at § 411.354(d)(2) and (3) to be applied when analyzing compliance with the requirements of the exceptions in § 411.357, including the exception for indirect compensation arrangements at § 411.357(p) (66 FR 876 through 878).

Following the publication of Phase I, we received comments regarding the interplay of the definition of ''indirect compensation arrangement,'' the exception at § 411.357(p) for indirect compensation arrangements, and the special rules that deem unit-based compensation not to take into account the volume or value of referrals or other business generated at § 411.354(d)(2) and (3), respectively, when certain conditions are met. The commenters questioned whether an indirect compensation arrangement exists at all if a referring physician receives time-based or unit-of-service based compensation that is fair market value and does not vary over the term of the arrangement—that is, compensation that, by definition, does not take into account the volume or value of referrals or other business generated under § 411.354(d)(2) and (3). Commenters noted that, similarly, the exception for indirect compensation arrangements at § 411.357(p), like § 411.354(d)(2) and (3), does not look to aggregate compensation and incorporates a fair market value test. Given this, the commenters pointed out that the ultimate result would be the same whether time-based and unit-of-service based compensation arrangements are initially excluded from the definition of ''indirect compensation arrangement'' at § 411.354(c)(2) or included in the definition and then excepted under § 411.357(p) after applying the special rules at § 411.354(d)(2) and (3). In response, we stated that, although we agree that the ultimate result may be the same—time, unit-of-service, or other ''per click'' based arrangements are generally permitted if they are at fair market value without reference to referrals—we believe that [the Phase I regulatory] construct more closely corresponds to the statutory treatment of direct compensation arrangements (69 FR 16059). We elected to retain the regulatory structure finalized in Phase I, noting a two-fold intent. We stated that we intended to include in the definition of ''indirect compensation arrangement'' any compensation arrangements (including time-based or unit-of-service based compensation arrangements) where the aggregate compensation received by the referring physician varies with, or otherwise takes into account, the volume or value of referrals or other business generated between the parties, regardless of whether the individual unit of compensation qualifies under § 411.354(d)(2) and (3) (69 FR 16059). We continued that we intended to exclude under the exception at § 411.357(p) that subset of indirect compensation arrangements where the compensation is fair market value and does not reflect the volume or value of referrals or other business generated (and the other requirements of the exception are satisfied). We stated that per-unit compensation will meet this test if it complies with the conditions of § 411.354(d)(2) and (3).

In developing our response to the commenters to the proposed rule, we revisited the regulatory construct for determining which unbroken chains of financial relationships between entities and physicians (or immediate family members of a physician) establish indirect compensation arrangements and how to determine if they pose a risk of program or patient abuse. One of the driving goals of this final rulemaking, which is a shared goal of the Patients over Paperwork initiative and the Regulatory Sprint, is to reduce unnecessary burden on providers and suppliers. As we discussed in section I.D. of this final rule, our final policies are intended to balance genuine program integrity concerns against the considerable burden of the physician self-referral law's referral and billing prohibitions. We see no need to continue to treat compensation arrangements that may qualify as ''indirect compensation arrangements'' in the exact same way that the statute treats direct compensation arrangements

when that construct creates unnecessary burden on the regulated industry. We believe that it is possible to simplify the analysis of whether an unbroken chain of financial relationships between an entity and a physician (or immediate family member of a physician) poses a risk of program or patient abuse without raising program integrity concerns, and we are finalizing revisions to the regulations at § 411.354(c)(2) that we believe achieve the same result as the Phase I regulatory construct in protecting against program or patient abuse but reduce unnecessary burden on the regulated industry.

We are revising our regulations at § 411.354(c)(2)(ii) to effectively incorporate and apply the conditions of the special rules on unit-based compensation at the definitional level when determining whether an indirect compensation arrangement exists that must satisfy the requirements of an applicable exception in order to avoid the prohibitions of the physician self-referral law. Unless all the elements of final § 411.354(c)(2)(i), (ii) and (iii) exist, the unbroken chain of financial relationships between an entity furnishing designated health services and a physician (or immediate family member of a physician) will not be considered an indirect compensation arrangement. Nor will the unbroken chain of financial relationships be considered a direct compensation arrangement under § 411.354(c)(1). Therefore, the referral and billing prohibitions of the physician self-referral law will not apply. Under the regulations finalized in this final rule, an unbroken chain of financial relationships between an entity and a physician will be considered an indirect compensation arrangement if the physician (or immediate family member of the physician) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the physician for the entity furnishing the designated health services, *and* any of the following are true: (1) The individual unit of compensation received by the physician (or immediate family member) is not fair market value for items or services actually provided; (2) the individual unit of compensation received by the physician (or immediate family member) is calculated using a formula that includes the physician's referrals to the entity furnishing designated health services as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; *or* (3) the individual unit of compensation received by the physician (or immediate family member) is calculated using a formula that includes other business generated by the physician for the entity furnishing designated health services as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity. In addition, the entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity.

We acknowledge that our final policies will reduce the number of unbroken chains of financial relationships that fall within the ambit of the physician self-referral law as indirect compensation arrangements (although they may still implicate the anti-kickback statute, depending on the facts and circumstances). We also acknowledge that, by analyzing unit-based compensation at the definitional stage at final § 411.354(c)(2)(ii), many unbroken chains of financial relationships will no longer be required to satisfy the writing requirement at § 411.357(p)(2), potentially limiting our and law enforcement's visibility into the compensation received by physicians who make referrals for designated health services to the entities at the other end of the unbroken chain of financial relationships between them. However, as we have stated many times in previous rulemakings and in this final rule, we believe that it is a common practice (if not the best practice), and required by other Federal and State statutes and regulations, for parties to reduce their arrangements to writing, including the compensation and other terms of their arrangements. Also, we remind readers that compliance with the physician self-referral law is a prerequisite for submitting a claim to Medicare for a designated health service referred by a physician who has (or whose immediate family member has) a financial relationship with the entity submitting the claim. Included in the burden of proof to show that a claim for designated health services is permissible is the burden to show either that the physician self-referral law does not apply because the parties do not have a financial relationship within the meaning of the physician self-referral law or, if the law does apply because the parties have a financial relationship within the meaning of the physician self-referral law, that all the requirements of an applicable exception are satisfied. An entity's mistaken belief that no indirect compensation arrangement exists does not eliminate the need to satisfy the requirements of an applicable exception to the physician self-referral law.

Comment: One commenter requested that we deem certain compensation formulas that *do* include the physician's referrals to an entity or other business generated by a physician for the entity as a variable to nonetheless *not* take into account the volume or value of referrals or other business generated if the compensation arrangement is consistent with value-based care goals but does not qualify for or satisfy the requirements of the new exceptions at § 411.357(aa).

Response: We decline to permit any arrangement under which compensation is determined using a formula that includes a physician's referrals to or other business generated for the entity as a variable and creates the positive or negative correlation with the compensation paid to or from the physician, as applicable. If a compensation arrangement does not qualify for or does not satisfy all the requirements of an exception at new § 411.357(aa), the compensation paid under the arrangement may not take into account the volume or value of the physician's referrals or other business generated by the physician for the entity. Although the new exceptions at § 411.357(aa) do not include a requirement that the compensation does not take into account the volume or value of a physician's referrals or other business generated by the physician, they include substitute safeguards against program or patient abuse through their limited application and included requirements. Permitting an arrangement to circumvent those safeguards and the volume or value and other business generated standards of the traditional exceptions would pose a risk of program or patient abuse.

Comment: One commenter requested clarification of the term ''other business generated.'' The commenter stated that industry guidance suggests that other business generated means services that are not designated health services. The commenter proposed that the definition of ''other business generated'' should include only services paid by government payors, and should not

extend to services paid by private or commercial payors.

Response: Our interpretation of the term ''other business generated'' is longstanding and settled. In Phase I, we stated that, based on our review of the legislative history, we believe that the Congress intended the ''other business generated'' language to be a limitation on the compensation or payment formula parallel to the statutory and regulatory prohibition on taking into account referrals of designated health services. We further stated that, in the provisions in which the phrase appears, affected payments cannot be based or adjusted in any way on referrals of designated health services or on any other business referred by the physician, including other Federal and private pay business (66 FR 877). We see no reason to revisit this interpretation as suggested by the commenter.

Comment: A few commenters objected to our proposals to establish special rules on the volume or value standard and the other business generated standard based on what appear to be fair market value concerns. The commenters provided the example of a hospital that determines the amount of fixed-rate compensation at a higher level than a physician practice might pay the physician because the hospital knows that it can direct the physician's referrals to the hospital and its affiliates to ''make up the difference'' in billings for those services.

Response: We assume the commenters are referring to compensation that is based on the physician's personally performed services and not referrals of designated health services or other business generated by the physician for the entity paying the compensation, for instance, a salary of $300,000 per year. Although the formula for calculating fixed-rate compensation for a physician's personally performed services would not include the physician's referrals to the entity or other business generated by the physician for the entity as variables—in our example, the physician's compensation would be $300,000 × the number of years of the arrangement's duration—the compensation arrangement must satisfy all the requirements of an applicable exception in order not to trigger the referral and billing prohibitions of the physician self-referral law. Compensation that is inflated to recognize the ability of the hospital to receive payment under the IPPS and OPPS for designated health services that it requires the physician to refer to the hospital or a specific provider, practitioner, or supplier within the hospital's health system may not be fair market value for the physician's personally performed services under our existing definition of ''fair market value'' and the revised definition of ''fair market value'' finalized in this final rule. See section II.B.5. of this final rule for a detailed discussion of our final policies with respect to the definition of ''fair market value.'' Also, as described above and in more detail in section II.B.4. of this final rule, if any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement must satisfy the conditions of § 411.354(d)(4).

4. Patient Choice and Directed Referrals (§ 411.354(d)(4))

Historically, when the conditions of the special rule at § 411.354(d)(4) are met, compensation from a *bona fide* employer, under a managed care contract, or under a personal service arrangement is deemed not to take into account the volume or value of referrals, even if the physician's compensation is predicated, either expressly or otherwise, on the physician making referrals to a particular provider, practitioner, or supplier. This special rule was established in Phase I after many commenters objected to our statement in the 1998 proposed rule that fixed payments to a physician could be considered to take into account the volume or value of referrals if a condition or requirement for receiving the payment was that the physician refer designated health services to a given entity, such as an employer or an affiliated entity (63 FR 1700). In Phase I, we acknowledged that the proposed interpretation could have had far-reaching effects, especially for managed care arrangements and group practices (66 FR 878). We determined that we would not consider a physician's compensation to take into account the volume or value of his or her referrals, as long as the directed referral requirement does not apply if a patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment (66 FR 878). In addition, the referral requirement must be set out in writing and signed by the parties, and the compensation to the physician must be: (1) Set in advance for the term of the compensation arrangement; and (2) consistent with fair market value for the services performed. Finally, the compensation arrangement must otherwise comply with an applicable exception in § 411.355 or § 411.357.

We continue to believe in the importance of preserving patient choice, protecting the physician's professional medical judgment, and avoiding interference in the operations of a managed care organization. In the proposed rule, we expressed concern that, given our proposed interpretation of the volume or value standard, § 411.354(d)(4) may apply in fewer instances, if at all, to serve these important goals. To reiterate how critical these protections are, we proposed to include in the exceptions applicable to the types of contracts or arrangements to which the special rule has historically applied an affirmative requirement that the compensation arrangement meet the conditions of the special rule at § 411.354(d)(4). To that end, we proposed to include in the exceptions at § 411.355(e) for academic medical centers, § 411.357(c) for *bona fide* employment relationships, § 411.357(d)(1) for personal service arrangements, § 411.357(d)(2) for physician incentive plans, § 411.357(h) for group practice arrangements with a hospital, § 411.357(l) for fair market value compensation, and § 411.357(p) for indirect compensation arrangements, a requirement that, in addition to satisfying the other requirements of the exception, the relevant arrangement must comply with the conditions of the revised special rule at § 411.354(d)(4). In making this proposal, we relied on the authority granted to the Secretary under sections 1877(b)(4), (e)(2)(D), (e)(3)(A)(vii), (e)(3)(B)(i)(II), and (e)(7)(vii) of the Act. We solicited comment as to whether, given the nature of academic medical centers, the conditions of revised § 411.354(d)(4) are necessary. We are finalizing our proposal to include an affirmative requirement that the compensation arrangement meet the conditions of the special rule at § 411.354(d)(4) in all of the exceptions identified in the proposed rule. As explained in section II.E.1. of this final rule, we are also finalizing this requirement in the new exception for limited remuneration to a physician at § 411.357(z). Although the requirement is not included in the new exceptions for value-based arrangements at final § 411.357(aa), as discussed in section II.A.2. of this final rule, we have incorporated into these exceptions specific requirements related to remuneration paid to a physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier.

In the 1998 proposed rule, highlighting stakeholder inquiries

regarding whether an arrangement fails to meet the volume or value standard only in situations in which a physician's payments from an entity fluctuate in a manner that reflects referrals, we expressed our view that an arrangement can also fail to meet this standard in some cases when a physician's payments from an entity are stable, but predicated, either expressly or otherwise, on the physician making referrals to a particular provider. We gave the example of a hospital that includes as a condition of a physician's employment the requirement that the physician refer only within the hospital's own network of ancillary service providers, such as to the hospital's own home health agency. We stated that, in these situations, a physician's compensation reflects the volume or value of his or her referrals in the sense that the physician will receive no future compensation if he or she fails to refer as required. We continue to believe that conditioning a physician's future compensation on his or her referrals could improperly influence the physician's medical decision making, potentially impacting patient choice or the utilization of services. However, upon further examination of the policy goals behind our statements in the 1998 proposed rule (63 FR 1700), the special rule finalized in Phase I (66 FR 878), and the comments on the proposed rule, we no longer believe that compensation predicated, either expressly or otherwise, on the physician making referrals of designated health services to a particular provider, practitioner, or supplier should be evaluated for compliance with the volume or value standard.

As described in the proposed rule (84 FR 55789) and in section II.B.3. of this final rule, after reviewing the statute and our regulations in a fresh light, we now believe that the volume or value standard is most appropriately interpreted as relating to how compensation is calculated; that is, what formula is used to determine the amount of the physician's compensation. We are finalizing special rules at § 411.354(d)(5)(i) and (6)(i) that set forth mathematical formulas that identify compensation that takes into account the volume or value of a physician's referrals. However, a review of the mathematical formula that determines the amount of the physician's compensation would not be sufficient to identify a referral requirement that could lead to program or patient abuse. Rather, payment conditioned on the physician's referrals of designated health services to a given entity, such as an employer or an affiliated entity, should be evaluated for compliance with the special rule at § 411.354(d)(4), which is mandatory under the policies finalized in this final rule.

As we explained in the proposed rule (84 FR 55794) and our response to comments in section II.B.3. of this final rule, there is a risk of program or patient abuse when a physician will receive no future compensation if he or she fails to refer as required. The same is true if the amount of the physician's compensation is tied to the physician's referral to a particular provider, practitioner, or supplier. To address this risk, we are revising § 411.354(d)(4) to include a condition at § 411.354(d)(4)(vi) that neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. This condition must be met regardless of whether the physician's compensation takes into account the volume or value of his or her referrals to the entity with which the physician has the compensation arrangement. As applied, under final § 411.354(d)(4)(vi), where an entity requires a physician to refer patients for designated health services to a particular provider, practitioner, or supplier and the applicable exception requires compliance with § 411.354(d)(4), in addition to meeting the other conditions of § 411.354(d)(4), neither the existence of the compensation arrangement nor the amount of the compensation may be contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

In the proposed rule, we described this type of contingency as a direct ''if X, then Y'' correlation (84 FR 55794). The proposed special rule built upon the concerns described above, which we originally described in the 1998 proposed rule as relating to a nexus between fixed-rate compensation and the volume or value of a physician's compensation. We believe that the condition at final § 411.354(d)(4)(vi) provides a clearer standard for stakeholders and better addresses our concerns than the proposed special rule that would have considered fixed-rate compensation to take into account the volume or value of referrals if there is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

We provide the following example to illustrate the application of our final regulation at § 411.354(d)(4)(vi). Assume that a hospital directly employs a cardiologist to treat patients in the hospital's outpatient cardiology department. The physician is paid a predetermined, unvarying annual salary. Under the employment arrangement, the hospital requires the physician to refer patients to the hospital or other providers and suppliers wholly owned by the hospital, unless the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. When negotiating an extension of the employment arrangement and revised compensation terms, the hospital reviews the past performance of the physician, including the physician's referrals for diagnostic testing. At final § 411.357(c)(5), the exception for *bona fide* employment relationships requires compliance with the conditions of the special rule for directed referrals at § 411.354(d)(4). (The exceptions for personal service arrangements and fair market value compensation have identical requirements at § 411.357(d)(1)(viii) and (l)(7), respectively.) Under § 411.354(d)(4)(vi), the amount of the physician's compensation may not be contingent on the number or value of the physician's referrals under the directed referral requirement. Thus, if, for example, the hospital increases the physician's compensation in the renewal term only if the physician made a targeted number of referrals for diagnostic testing to the hospital or the designated wholly-owned providers and suppliers in the current term, the compensation would not meet the condition at § 411.354(d)(4)(vi). Similarly, if, for example, the hospital refuses to renew the employment arrangement (or terminates it in the current term) unless the value of the physician's diagnostic testing referrals generates sufficient profit to the hospital (or its wholly-owned providers and suppliers), the existence of the compensation arrangement would be contingent on the value of the physician's referrals in violation of § 411.354(d)(4)(vi).

We also proposed to revise § 411.354(d)(4) to eliminate certain language regarding: (1) Whether the ''set in advance'' and ''fair market value'' conditions of the special rule apply to the compensation arrangement (as stated in the regulation) or to the compensation itself; and (2) when compensation is considered fair market value. The proposed revisions were intended to clarify that the physician's *compensation* must be set in advance. Any changes to the compensation (or the formula for determining the compensation) must also be set in advance (that is, made prospectively). (See section II.D.5. of this final rule for a detailed discussion of the ''set in advance'' deeming provision at § 411.354(d)(1).) We proposed to clarify that the physician's *compensation* must be consistent with the fair market value of the services performed. In addition, we proposed to eliminate the parenthetical language in existing § 411.354(d)(4) as it conflates the concept of fair market value and the volume or value standard. As noted in response to the comment in section II.B.1. of this final rule, these are separate standards, and compliance with one is not contingent on compliance with the other. We also proposed nonsubstantive revisions for clarity. We noted that, although revised § 411.354(d)(4) sets forth protections that apply to both the compensation arrangement that includes a directed referral requirement and also specifically to the compensation itself, for continuity in the application of the regulation, we would leave the regulation in § 411.354(d), which sets forth special rules on *compensation,* rather than include it in § 411.354(e), which sets forth special rules for *compensation arrangements.* We are finalizing the proposed restructuring of and nonsubstantive revisions to § 411.354(d)(4).

We received the following comments and our responses follow.

Comment: Many commenters recognized that directed referral requirements would be permitted without limitation if we finalized our proposed interpretation of the volume or value standard at § 411.354(d)(5). Commenters agreed that compliance with the conditions of the special rule at § 411.354(d)(4) provides important protections for patients and the independence of a physician's medical decision making. Several commenters supported our proposal to continue this protection by including in the exceptions at § 411.355(e) for academic medical centers, § 411.357(c) for *bona fide* employment relationships, § 411.357(d)(1) for personal service arrangements, § 411.357(d)(2) for physician incentive plans, § 411.357(h) for group practice arrangements with a hospital, § 411.357(l) for fair market value compensation, and § 411.357(p) for indirect compensation arrangements an affirmative requirement for compliance with § 411.354(d)(4) when a physician's compensation is conditioned on his or her referrals to a particular provider, practitioner, or supplier.

Response: We agree with the commenters that patient choice, independent medical decision making, and avoiding interference with managed care contracts should be protected. We are finalizing our proposals and, as discussed in section II.E.1. of this final rule, are including the requirement in the new exception for limited remuneration to a physician at § 411.357(z). As the previous commenter described, directed referral requirements can take the form of conditioning the *existence* of the arrangement itself on the physician's referrals to a particular provider, practitioner, or supplier, or they may condition the *amount* of the physician's compensation on his or her referrals to a particular provider, practitioner, or supplier. Because both types of conditioning represent threats to patient choice and the independence of a physician's medical decision making, in order to reflect both of these conditioning requirements, we are revising the language of § 411.354(d)(4), with which the compensation arrangement must comply under the exceptions at §§ 411.355(e) and 411.357(c), (d)(1), (d)(2), (h), (l), (p), and (z). In each of the exceptions noted, if the physician referrals are directed to a particular provider, practitioner, or supplier, the arrangement must satisfy the conditions of § 411.354(d)(4).

Comment: A few commenters stated that they did not oppose the policy stated in the proposed rule (84 FR 55796) that § 411.354(d)(4) applies to both the situation where the compensation *arrangement* is contingent on the physician's required referrals and the situation where the compensation *amount* is contingent on the physician's required referrals, but requested guidance on the precise function of the special rule at § 411.354(d)(4) in light of our proposed interpretation of the volume or value standard. One of these commenters focused on the contractual terms between the parties to the compensation arrangement, and asked whether the volume or value standard would be violated if the breach of a directed referral requirement resulted only in termination of the arrangement, rather than an impact on the amount of the physician's compensation from the entity. This commenter provided a second example of a directed referral requirement that it stated would affect the amount of a physician's compensation. Under that example, a physician is paid different stipulated percentages of a bonus pool depending on the percentage of the physician's referrals that are ''in network'' (that is, to a particular provider, practitioner, or supplier). The commenter requested clarification of the applicability of the special rule at § 411.354(d)(4) and whether provisions such as those described would violate the volume or value standard as proposed. A different commenter described a compensation arrangement under which a physician is paid an amount that does not result from a mathematical model tied to individual referrals of designated health services, but rather a ''model'' under which the entity knows it will generate revenue by requiring physician referrals to a particular provider, practitioner, or supplier. The commenter stated that, under the scenario presented, the entity is not rewarding (paying) the physician for referrals but would terminate the physician's employment if he or she does not actively participate in the mandated referrals. The commenter asked whether CMS views this type of compensation model as taking into account the volume or value of the physician's referrals.

Response: In light of this specific comment and other similar comments, we revisited the history of § 411.354(d)(4) and our previously-stated concerns regarding directed referral requirements that ultimately led to the establishment of the special rule. As we stated in Phase I, we understand that directed referral requirements are a common and integral part of employment relationships, personal service arrangements, and managed care contracts (66 FR 878). Even so, we continue to believe that payments tied to referral requirements can be abused, and appropriate safeguards should be in place to protect against the risk of program or patient abuse when an entity directs a physician where to make referrals of designated health services. After review of the regulatory history of our interpretation of the volume or value standard and the establishment of the special rule at § 411.354(d)(4), we now believe that the best approach to addressing the risks of directed referral requirements is to affirmatively require compliance with the conditions of

§ 411.354(d)(4) whenever an entity conditions the compensation of a physician with whom it has an employment relationship, personal service arrangement, or managed care contract on the physician's referrals for designated health services to a particular provider, practitioner, or supplier. Compensation conditioned, either expressly or otherwise, on the physician making referrals of designated health services to a particular provider, practitioner, or supplier should not be evaluated for compliance with the volume or value standard. Because we are finalizing requirements in certain exceptions for affirmative compliance with the conditions of § 411.354(d)(4), and directed referral requirements will no longer be considered in the context of compliance with the volume or value standards, we are applying the condition at final § 411.354(d)(4)(vi), rather than the final regulation at § 411.354(d)(5)(i), in our response to the commenters.

The condition at § 411.354(d)(vi) applies to a directed referral requirement which, if not achieved, would result in the termination of a physician's compensation arrangement, even if it would not impact the amount of the physician's compensation from the entity. The condition at § 411.354(d)(4)(vi) prohibits making the existence of a compensation arrangement contingent on the *number* or *value* of the physician's referrals to a particular provider, practitioner, or supplier. If the compensation arrangement would be terminated if the physician failed to refer a sufficient number of patients for designated health services, or if the value of the physician's referrals of designated health services failed to achieve the target established under the directed referral requirement, the directed referral requirement would be impermissible and the compensation arrangement would not satisfy the applicable exception's requirement of compliance with § 411.354(d)(4). We emphasize that § 411.354(d)(4)(vi) does not prohibit directed referral requirements based on an established percentage—rather than the number or value—of a physician's referrals. Therefore, if the directed referral requirement in the commenter's example provided for termination of the compensation arrangement if the physician failed to refer 90 percent, for example, of his or her patients to a particular provider, practitioner, or supplier, it would not run afoul of the special rule at § 411.354(d)(4) or jeopardize compliance with the requirement of the applicable exception.

With respect to the commenter's second example that ties the amount of the physician's compensation to achievement of a directed referral requirement, the condition at § 411.354(d)(4)(vi) would apply in the same manner. A directed referral requirement under which a physician is paid different stipulated percentages of a bonus pool depending on the *percentage* of the physician's referrals that are ''in network'' (that is, to a particular provider, practitioner, or supplier) would not be categorically prohibited under § 411.354(d)(4)(vi); however, we caution that the composition of the bonus pool must be analyzed to ensure that the formula for the compensation ultimately paid to the physician does not include referrals of designated health services or other business generated by the physician as a variable. Also, if the directed referral requirement was tied to the number or value of the physician's referrals, it would run afoul of the special rule at § 411.354(d)(4) and and the compensation arrangement would not satisfy the applicable exception's requirement of compliance with § 411.354(d)(4).

Comment: One commenter expressed support for the affirmative requirement for compliance with the conditions of § 411.354(d)(4) where a physician is directed to refer patients to a particular provider, practitioner, or supplier under the physician's compensation arrangement with the entity directing the referrals. The commenter recommended that we finalize our proposal to make the compliance requirement mandatory, and that we apply the rule where the referral requirement is not only express, but where it occurs as the practical result of processes that steer a physician's referrals for designated health service to a provider, practitioner, or supplier selected by the entity.

Response: The affirmative obligation finalized in the exceptions at §§ 411.355(e) and 411.357(c), (d)(1), (d)(2), (h), (l), (p), and (z) is not limited to express or written requirements to refer patients to particular provider, practitioner, or supplier selected by the entity paying the compensation. Rather, the condition at § 411.354(d)(4)(vi), as finalized, prohibits making the existence of the compensation arrangement or any compensation paid to the referring physician contingent on the physician's referrals to a particular provider, practitioner, or supplier.

Comment: One commenter expressed general agreement with the proposals to include compliance with the conditions of § 411.354(d)(4) as an affirmative requirement in exceptions applicable to compensation for physician services in those instances where the physician's compensation is conditioned on the physician's referrals to a particular provider, practitioner, or supplier. The commenter also supported leaving the regulation in § 411.354(d)(4), rather than include it with other special rules related to compensation arrangements at § 411.354(e).

Response: We are finalizing our proposals with the modifications explained in the responses to other comments. We agree with the commenter that the regulation should remain at § 411.354(d)(4). We believe this will avoid disruption with stakeholder compliance efforts and our enforcement efforts.

Comment: One commenter urged CMS not to adopt an affirmative requirement to comply with the conditions of § 411.354(d)(4) when a physician's compensation is conditioned on the physician's referrals to a particular provider, practitioner, or supplier. Despite its stated support for patient preference in referrals, the commenter asserted that the requirement would place additional burden on physicians and other providers.

Response: Where such referral requirements have existed, they have historically implicated the volume or value standard under our historic interpretation of that standard. Thus, parties would have had to comply with the conditions of § 411.354(d)(4) in order to be assured not to run afoul of the volume or value standard, or offer some other proof of compliance with the volume or value standard. This is not a new requirement.

Comment: A few commenters discussed what they termed ''employee workplace requirements'' that require an employed physician to treat the employer's patients in a specified workplace, typically the location of a medical practice or clinic and the address of an affiliated hospital. The commenters questioned whether such requirements were of concern to CMS. The commenters requested that CMS provide guidance on employee workplace requirements, suggesting that several approaches might be appropriate. The commenters offered that CMS could take the position that employee workplace requirements are not directed referral requirements that trigger the need for compliance with the volume or value standard because the employed physician is merely restricted by his or her employment from working

elsewhere and is not expressly required to refer patients to the employer. In the alternative, the commenters offered that CMS could take the position that such workplace requirements are directed referral requirements because the employer is effectively requiring the physician to refer his or her patients to the employer and, for example, an affiliated hospital for designated health services. If so, the commenters requested that CMS confirm that § 411.354(d)(4) requires only that the employer permits the physician to refer the patient to another physician who can provide the services (such as a surgery or other procedure) at a different location based on patient preference, payor requirements, or the best medical interest of the patient. The commenters requested specific confirmation that § 411.354(d)(4) does not require the employer to permit the employed physician to personally treat the patient in a location other than that specified in the physician's employment contract.

Response: Under the policies finalized in this final rule, a directed referral requirement will not trigger analysis for compliance with the volume or value standard at final § 411.354(d)(5). However, a compensation arrangement will have to satisfy the conditions of § 411.354(d)(4) if any of the physician's compensation is conditioned on the physician's referrals to a particular provider, practitioner, or supplier and the parties intend to rely on the exception at § 411.355(e) or § 411.357(c), (d)(1), (d)(2), (h), (l), (p), or (z). The commenter is correct that the requirement to comply with § 411.354(d)(4) is not intended to interfere with employer's rights or operations or infringe on the employer-employee relationship. The condition at § 411.354(d)(4)(iv)(B) requires only that the requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. Requiring that the employed physician refer the patient to another physician for treatment is permissible, provided that the referral is appropriate. We wish to make clear that the permissibility of the referral to another physician for purposes of the physician self-referral law has no bearing on whether the employed physician complies with any State law and common law requirements, such as laws regarding patient abandonment.

Comment: Many commenters noted that the term ''referrals'' is used throughout our physician self-referral regulations. Commenters stated that, although the term is defined at § 411.351, they were uncertain whether the term ''referrals'' has the meaning ascribed to it at § 411.351 in all instances in which it appears in the regulations. Several commenters asked if the term ''referrals'' in § 411.354(d)(4) is intended to encompass more than the defined term ''referrals'' at § 411.351. One commenter stated that, if the meaning of ''referrals,'' as used at § 411.354(d)(4), is not limited to the definition at § 411.351, the proposed inclusion of a requirement for compliance with the conditions of § 411.354(d)(4) as an element of the exceptions for *bona fide* employment relationships, personal service arrangements, and others has the effect of introducing an all-payor volume or value standard into these exceptions. The commenters requested that CMS expressly clarify in commentary that, unless otherwise noted, when ''referrals'' appears in the physician self-referral regulations, it has the meaning set forth at § 411.351.

Response: The introductory language to § 411.351 states clearly that, unless the context indicates otherwise, the term ''referral'' has the meaning set forth in § 411.351. The term ''referral,'' as used at § 411.354(d)(4) and the new requirement in certain exceptions that, if remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4) have the meaning set forth in the definition of ''referral'' at § 411.351. In Phase I, we discussed the scope of the term ''referral'' with reference to a requirement that a physician refer designated health services to a given entity (66 FR 878). As we stated above in section II.B.2. of this final rule, unless the context indicates otherwise, the term ''referral'' has the meaning set forth in § 411.351 throughout the physician self-referral regulations, including in the special rules on compensation at § 411.354(d).

5. Fair Market Value (§ 411.351)

The term ''fair market value,'' as it is defined at section 1877(h)(3) of the Act, consists of three basic components. Fair market value is defined generally as ''the value in arms length [sic] transactions, consistent with the general market value.'' The statutory definition includes additional qualifications for leases generally, providing that fair market value with respect to rentals or leases also means ''the value of rental property for general commercial purposes (not taking into account its intended use).'' Finally, with respect to the lease of office space, in particular, the statutory definition further stipulates that fair market value also means that the value of the rental property is ''not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.'' Most of the statutory exceptions at section 1877(e) of the Act relating to compensation arrangements include requirements pertaining to fair market value compensation, including the exceptions for the rental of office space, the rental of equipment, *bona fide* employment relationships, personal service arrangements, isolated transactions, and payments by a physician. Many of the regulatory exceptions created using the Secretary's authority under section 1877(b)(4) of the Act also include requirements pertaining to fair market value compensation, including the exceptions for academic medical centers, fair market value compensation, indirect compensation arrangements, EHR items and services, and assistance to compensate a nonphysician practitioner.

The term ''fair market value'' is defined in our regulations in § 411.351. In the 1992 proposed rule (57 FR 8602) and the 1995 final rule (60 FR 41978), we incorporated the statutory definition of ''fair market value'' into our regulations without modification. In the 1998 proposed rule (63 FR 1686), we proposed to include in our definition of ''fair market value'' a definition of ''general market value,'' to explain what it means for a value to be ''consistent with the general market value.'' In an attempt to ensure consistency across our regulations, we proposed to adopt the definition of ''general market value'' from part 413 of our regulations, which pertains to reasonable cost reimbursement for end stage renal disease services. In the context of determining the cost incurred by a present owner in acquiring an asset, § 413.134(b)(2) defined ''fair market value'' as ''the price that the asset would bring by *bona fide* bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price is the price that *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition.'' We modified the

definition drawn from § 413.134(b)(2) to include analogous provisions for determining the fair market value of any items or services, including personal services, employment relationships, and rental arrangements. As proposed in the 1998 proposed rule, ''general market value'' would mean:

The price that an asset would bring, as the result of *bona fide* bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement, as the result of *bona fide* bargaining between well-informed parties to the agreement, on the date of acquisition of the asset or at the time of the service agreement. Usually the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement.

The proposed definition of ''fair market value'' in the 1998 proposed rule did not substantively modify the provisions of the fair market value definition pertaining to leases in general and office space leases in particular.

In Phase I, we finalized the definition of ''fair market value'' from the 1998 proposed rule with one modification (66 FR 944 through 945). The definition of ''fair market'' value finalized in Phase I clarified that a rental payment ''does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.'' In Phase I we also responded to commenters that requested guidance on how to determine fair market value in a variety of circumstances. We stated that we would accept any commercially reasonable method for determining fair market value. However, we noted that, in most exceptions, the fair market value requirement is further modified by language that precludes taking into account the volume or value of referrals, and, in some cases, other business generated by the referring physician. We concluded that, in determining whether compensation is fair market value, requirements pertaining to the volume or value of referrals and other business generated may preclude reliance on comparables that involve entities and physicians in a position to refer or generate business (66 FR 944). Elsewhere in Phase I, we suggested a similar underlying connection between the fair market value requirement and requirements pertaining to the volume or value of a physician's referrals and other business generated (66 FR 877). In a discussion of our then-interpretation of the fair market value standard in light of our Phase I interpretation of the requirement that compensation not take into account other business generated, we stated that—

[T]he additional limiting phrase 'not taking into account * * * other business generated between the parties' means simply that the fixed, fair market value payment cannot take into account, or vary with, referrals of Medicare or Medicaid [designated health services] or any other business generated by the referring physician, including other Federal and private pay business. Simply stated, section 1877 of the Act establishes a straightforward test that compensation arrangements should be at fair market value for the work or service performed or the equipment or space leased—not inflated to compensate for the physician's ability to generate other revenues.

Despite our intimation in Phase I that the concepts of fair market value and the volume and value of referrals or other business generated were fundamentally interrelated, the definition of fair market value finalized in Phase I did not include any reference to the volume or value of a physician's referrals.

In Phase II, we made two significant modifications to the definition of ''fair market value.'' First, we proposed certain ''safe harbors'' for determining fair market value for hourly payments made to physicians for physician services (69 FR 16092 and 16107). (These safe harbors were not finalized.) Second, and more importantly, we incorporated into the definition of ''fair market value'' a reference to the volume or value standard found in many exceptions to the physician self-referral law. The Phase II definition of ''fair market value'' provided, in relevant part, that fair market value is usually the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. We explained our view that the determination of fair market value under the physician self-referral law differs in significant respects from standard valuation techniques and methodologies. In particular, we noted that the methodology must exclude valuations where the parties to the transactions are at arm's length but in a position to refer to one another (69 FR 16107). We made no substantive changes to the definition of ''fair market value'' in Phase III or in any of our subsequent rulemaking.

As a preliminary matter and as described previously in section II.B.1. of this final rule, a careful reading of the statute shows that the fair market value requirement is separate and distinct from the volume or value standard and the other business generated standard. (See section II.B.3. of this final rule for a detailed discussion of the volume or value standard and the other business generated standard.) The volume or value and other business generated standards do not merely serve as ''limiting phrases'' to modify the fair market value requirement. In order to satisfy the requirements of the exceptions in which these concepts appear, compensation must both: (1) Be fair market value for items or services provided; *and* (2) not take into account the volume or value of referrals (or the volume or value of other business generated by the physician, where such standard appears). We believe that the appropriate reading of the statute is that the requirement that compensation does not take into account the volume or value of referrals—which is plainly set out as an independent requirement of the relevant exceptions—is not also part of the definition of ''fair market value.'' We note that the statutory definition of ''fair market value'' at section 1877(h)(3) of the Act includes no reference to the volume or value of referrals (or other business generated between the parties or by the physician). For these reasons and as described further below, we are finalizing our proposal to eliminate the connection to the volume or value standard in the definitions of ''fair market value'' and ''general market value.''

Our proposals to revise the definition of ''fair market value'' at § 411.351 were premised on our goal to give meaning to the statutory language at section 1877(h)(3) of the Act. As described previously in this section II.B.5., the statute states a general definition of ''fair market value'' and then modifies that definition for application to leases of equipment and office space. One of the modifications applies to leases of both equipment and office space; the other applies only to the lease of office space. To illustrate this more clearly in our regulations, we proposed to modify the definition of ''fair market value'' to provide for a definition of general application, a definition applicable to the rental of equipment, and a definition

applicable to the rental of office space. (We proposed to use the terms ''rental'' of equipment and ''rental'' of office space as those are the titles of the statutory exceptions at section 1877(e)(1)(A) and (B) of the Act and our regulatory exceptions at § 411.357(a) and (b).) We are finalizing our proposals to restructure the regulation in this way. We believe that this approach provides parties with ready access to the definition of ''fair market value,'' with the attendant modifiers, that is applicable to the specific type of compensation arrangement at issue. Under the final regulation at § 411.351, generally, fair market value means the value in an arm's-length transaction, consistent with the general market value of the subject transaction. With respect to the rental of equipment, fair market value means the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction. And with respect to the rental of office space, fair market value means the value in an arm's length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction. We are not finalizing the proposed references to ''like parties and under like circumstances.'' We note that the structure of the final regulation merely reorganizes for clarity, but does not significantly differ from, the statutory language at section 1877(h)(3) of the Act.

We also proposed changes to the definition of ''general market value,'' which, until now, was included within the definition of fair market value at § 411.351. As we explained in the proposed rule, the definition of ''fair market value'' finalized in Phase II states the following, some of which relates to fair market value and some of which relates to the included term, ''general market value'' (84 FR 55797). Numerical references are added here for ease but did not appear in the regulation at § 411.351:

(1) Fair market value means the value in arm's-length transactions, consistent with the general market value.

(2) General market value means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.

(3) Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

(4) With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), ''fair market value'' means the value of rental property for general commercial purposes (not taking into account its intended use).

(5) In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.

(6) For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

Items one, four, and five essentially restate the language at section 1877(h)(3) of the Act, albeit with the intervening language in items two and three, and item six was added in Phase I in response to a comment for the purpose of interpreting the modifier ''(not taking into account its intended use)'' in item four and at section 1877(h)(3) of the Act. We stated in the 1998 proposed rule that items two and three were our attempt to give meaning to the statutory requirement that the fair market value of compensation must be ''consistent with the general market value.'' In doing so, we relied on a regulation that relates to the circumstances under which an appropriate allowance for depreciation on buildings and equipment used in furnishing patient care can be an allowable cost. We stated in the proposed rule that we no longer see the benefit of connecting the definition of ''general market value'' to principles of reasonable cost reimbursement for end stage renal disease services in order to explain what it means for a value to be consistent with general market value, as required by the statute. Moreover, the definition at § 413.134(b)(2) upon which we relied states that *fair* market value (not general market value) is defined as the price that the asset would bring by *bona fide* bargaining between well-informed buyers and sellers at the date of acquisition. The regulation goes on to state that, usually the fair market price is the price that *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition. This definition more closely ties to the widely accepted IRS definition of ''fair market value,'' [8] not general market value. Therefore, we considered whether current § 411.351 includes an appropriate definition for ''general market value.''

We stated in the proposed rule that we see no indication in the legislative history or the statutory language itself that the Congress intended that the definition of ''general market value'' for purposes of the physician self-referral law should deviate from general concepts and principles in the valuation community. We discussed in detail the basis for our proposals to revise the definition of ''general market value'' in accordance with our belief that the Congress used the term ''general market value'' to ensure that the fair market value of the remuneration is generally consistent with the valuation that would result using accepted valuation principles (84 FR 55798). However, after reviewing the comments, to which our detailed responses are provided below, we believe that our proposals, if finalized, could have had an unintended limiting effect on the regulated community, as well as the valuation community. Our use of the term ''market value'' in our preamble discussion, although not carried into the proposed definition of ''general market value,'' may have been inaccurate. Therefore, we are retracting our statements equating ''general market value,'' as that term appears in the statute and our regulations, with ''market value,'' the term we identified as uniformly used in the valuation industry (84 FR 55798).

[8] Fair Market Value is defined as ''the price at which the property would change hands between a willing buyer and a willing seller when the former is not under any compulsion to buy and the latter is not under any compulsion to sell, both parties having reasonable knowledge of relevant facts.'' (IRS Rev. Ruling 59–60)

We continue to believe that the general market value of a transaction is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another. Thus, for example, when parties to a potential medical director arrangement determine the value of the physician's administrative services, they must not consider that the physician could also refer patients to the entity when not acting as its medical director. After reviewing the comments on our proposed definition of ''general market value'' and the existing regulation at § 411.351, we determined that the best way to state this policy is to remove the language regarding the volume or value standard (item three above) and restructure the definition to emphasize our policy that the valuation of the remuneration terms of a transaction should not include any consideration of other business the actual parties to the transaction may have with one another. Also, for clarity and as supported by commenters, we are finalizing definitions of ''general market value'' specific to each of the types of transactions contemplated in the exceptions to the physician self-referral law—asset acquisition, compensation for services, and rental of equipment or office space. Under our final regulation at § 411.351, ''general market value'' means, with respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of *bona fide* bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other. With respect to compensation for services, ''general market value'' means the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other. And, with respect to the rental of equipment or the rental of office space, ''general market value'' means the price that rental property would bring at the time the parties enter into the rental arrangement as the result of *bona fide* bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

In the proposed rule, we stated that it is our view that the concept of *fair* market value relates to the value of an asset or service to hypothetical parties in a hypothetical transaction (that is, typical transactions for like assets or services, with like buyers and sellers, and under like circumstances), while *general* market value relates to the value of an asset or service to the actual parties to a transaction that is set to occur within a specified timeframe. We provided examples of compensation arrangements under which compensation outside the parameters of salary survey data could be appropriate (84 FR 55798 through 55799). Although we are not finalizing the proposed analytical framework related to ''hypothetical'' versus ''actual'' transactions, we continue to believe that the fair market value of a transaction—and particularly, compensation for physician services—may not always align with published valuation data compilations, such as salary surveys. In other words, the rate of compensation set forth in a salary survey may not always be identical to the worth of a particular physician's services. For this reason, we are affirming the examples provided in the proposed rule and restate them here, with modifications to eliminate terminology not included in our final analytical framework and regulations. As we stated in the proposed rule, extenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other valuation data compilations that are not specific to the actual parties to the subject transaction (84 FR 55799). By way of example, assume a hospital is engaged in negotiations to employ an orthopedic surgeon. Independent salary surveys indicate that compensation of $450,000 per year would be appropriate for an orthopedic surgeon in the geographic location of the hospital. However, the orthopedic surgeon with whom the hospital is negotiating is one of the top orthopedic surgeons in the entire country and is highly sought after by professional athletes with knee injuries due to his specialized techniques and success rate. Thus, although the employee compensation of a hypothetical orthopedic surgeon may be $450,000 per year, this particular physician commands a significantly higher salary. In this example, compensation substantially above $450,000 per year may be fair market value. On the other hand, hypothetical data may result in hospitals and other entities paying more than they believe appropriate for physician services. Assume a hospital is engaged in negotiations to employ a family physician. Independent salary surveys indicate that compensation of $250,000 per year would be appropriate for a family physician nationally; no local salary surveys are available. However, the cost of living in the geographic location of the hospital is very low despite its proximity to good schools and desirable recreation opportunities, and, due to declining reimbursement rates and a somewhat poor payor mix, the hospital's economic position is tenuous. Although the physician may request the $250,000 that the salary survey indicates would be appropriate for a hypothetical (unidentified) physician to earn, and the hospital may believe that it is compelled to pay the physician this amount, the fair market value of the physician's compensation may be less than $250,000 per year (84 FR 55799).

We also proposed to remove from the regulation text at § 411.351 the statement that, for purposes of the definition of ''fair market value,'' a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements (84 FR 55798). This language was added to the regulation text as a result of our response in Phase I to a commenter to the 1998 proposed rule, where we stated that a rental payment does not violate the requirement that the fair market value of rental property is the value of the property for general commercial purposes, not taking into account its intended use, merely because it reflects any costs that were incurred by the lessor in developing or upgrading the property, or maintaining the property or its improvements, regardless of why the improvements were added (66 FR 945). That is, the rental payment may reflect the value of any similar commercial property with improvements or amenities of a similar value, regardless of why the property was improved. This regulation text appears to have caused confusion among stakeholders. Although it remains our policy, to avoid further confusion and provide certainty in the final definitions of ''fair market value'' and ''general market value,'' we are finalizing our proposal to remove this language from the definition of ''fair market value'' at § 411.351.

Lastly, we noted in the proposed rule that many CMS RFI commenters requested that we simply return to the statutory language defining fair market value (84 FR 55798). Some commenters on the proposed rule made similar requests. We continue to disagree that this would be the best approach. We believe that it is important to provide guidance with respect to the requirement that compensation is fair market value in order not to stymy our

enforcement efforts (or those of our law enforcement partners). This guidance is also crucial to support the compliance efforts of the regulated industry.

We received the following comments and our responses follow.

Comment: Some commenters supported our proposal to remove the language regarding bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, suggesting that this language essentially links the volume or value standard with the definition of ''fair market value.'' The commenters noted that CMS clearly stated in the proposed rule that the volume or value standard and other business generated standard are distinct and separate requirements of many exceptions to the physician self-referral law (84 FR 55797). These commenters also referenced court opinions in which they believe the standards were blended or conflated by the court, causing confusion, additional litigation, and what they termed a ''torrent of unnecessary effort to reexamine arrangements long-believed to comply with the law.'' The commenters contended that parties should not have to search for market data that isolates transactions with physicians who are not in a position to refer to the entities with which they have compensation arrangements. In contrast, one commenter strongly opposed our proposal to remove the language regarding well-informed buyers and sellers that are not otherwise in a position to generate business for each other from the definition of ''general market value.'' A few other commenters asserted that, by defining general market value as the value determined by the parties to the subject transaction, the standard would simply be a subjective test of how parties to the transaction value the services, which could include additional payment for referrals or the generation of business. These commenters asserted that delinking the definition of ''general market value'' from the ability to generate business could result in the parties comparing the subject transaction to other transactions under which compensation is inflated by the value of referrals. One commenter suggested that we include in regulation text our preamble statement that [general] market value is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another (84 FR 55798). The commenter asserted that this would address the legitimate concern about valuations for purposes of the physician self-referral law being distorted by considerations of referrals. The commenter suggested that we include this statement at the end of the proposed definition of ''general market value'' for clarity.

Response: Although we disagree with the characterization of our proposal to define general market value merely as the value determined by the parties to the subject transaction, we find the program integrity concerns highlighted by the latter commenters compelling. It was not our intention to define ''general market value'' in a way that permits the inappropriate consideration of the value of a physician's referrals or the other business that a physician could generate for an entity in a determination of the fair market value of compensation. In Phase I, based on our then-interpretation that the ''volume or value restriction'' in the exceptions to the physician self-referral law established a limitation on the fair market value of compensation rather than represent a separate and distinct requirement of the exceptions, we stated that, depending on the circumstances, the ''volume or value'' restriction will preclude reliance on comparables that involve entities and physicians in a position to refer or generate business for each other (66 FR 944). In Phase II, we stated that, if parties are using comparables to establish fair market value, they should take reasonable steps to ensure that the comparables are not distorted (69 FR 16107). Although we have renounced the interpretation of the volume or value and other business generated standards as merely limiting or modifying the fair market value requirement (84 FR 55797), we continue to believe that precluding reliance on comparables that involve entities and physicians in a position to refer or generate business for each other in the determination of fair market value and general market value is an important program integrity safeguard. We are finalizing a definition of ''general market value'' that retains this language from the current regulation defining general market value. We believe this will be less disruptive to the regulated industry and valuation professionals that have developed compliance protocols and valuation standards that have incorporated this requirement for the past two decades, while still achieving our goal of disentangling the volume or value and other business generated standards from the requirement that compensation is fair market value. We are not including in the definition of ''general market value'' a statement that general market value is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another. Although we continue to believe that the determination of general market value should be based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another, we do not believe that it is necessary to include this statement because the final definition of ''general market value'' retains the essentially equivalent requirement for *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

Compensation to or from a physician should not be inflated or reduced simply because the entity paying or receiving the compensation values the referrals or other business that the physician may generate more than a different potential buyer of the items or services. This means that a hospital may not value a physician's services at a higher rate than a private equity investor or another physician practice simply because the hospital could bill for designated health services referred by the physician under the OPPS, whereas a physician practice owned by the private equity investor or other physicians would have to bill under the PFS, which may have lower payment rates. Put another way, the value of a physician's services should be the same regardless of the identity of the purchaser of those services. We recognize that reliance on similar transactions in the marketplace could simplify the process of determining fair market value for purposes of the physician self-referral law, but adopting such a standard would allow parties to consider the additional (or investment) value to certain types of entities, skewing the buyer-neutral fair market value.

Comment: One commenter asserted that the definition of ''fair market value'' should include a statement that organizations compensating individuals at an ongoing loss may create risk that the compensation is not representative of fair market value. The commenter explained its concern in an example involving a hospital compensating a physician at an amount greater than the collections for the physician's services, asserting that the hospital is able to do so because it controls referrals within its network and increased facility revenues offset the physician practice losses. In the commenter's view, this creates a situation in which hospitals are taking

into account the value of referrals when setting physician compensation. The commenter noted that, from a fair market value and [general] market value perspective, two hypothetical parties (that cannot consider the fact that one party can generate business for the other) would never enter into a situation in which the physician's compensation and benefits exceeded direct revenue. A different commenter asserted that a payment to a physician above what the entity collects for the physician's services is inherently not fair market value.

Response: We agree that, in some circumstances, an entity's compensation of a physician at an ongoing loss may present program integrity concerns, but see no need to include the language requested by the commenter in regulation. As we stated earlier, we are retaining the language ''not in a position to generate business'' in the definition of ''general market value.'' We believe this addresses the commenter's concern, at least in part, as it requires that the nature or identity of the purchaser of the items or services (in the commenter's example, the hospital) is irrelevant to a determination of ''general market value'' and, thus, ''fair market value.'' In the commenter's example, the value of the physician's services is the value to any willing buyer, and the fact that the hospital could make up losses for the physician's compensation through designated health services reimbursed at facility rates under OPPS rather than PFS, may not be considered. Also, we disagree that parties would *never* enter into such an arrangement. As we stated above in section II.B.2 (with respect to the definition of ''commercially reasonable''), there are many valid reasons and legitimate business purposes for entering into an arrangement that will not result in profit for one or more of the parties to the arrangement.

Comment: A few commenters raised the point that, with respect to our statements in the proposed rule connecting the statutory term ''general market value'' to the valuation principle of ''market value'' (84 FR 55798), ''general market value'' does not equate to the ''market value'' of a transaction, as that term is used in the valuation industry. One of these commenters suggested that what CMS described as ''market value'' actually corresponds to ''investment value'' as defined by the four commercial valuation disciplines: Business valuation, compensation valuation, machinery and equipment valuation, and real estate valuation. Commenters expressed concern that this focus would narrow the universe of appropriate valuation methodologies for purposes of the physician self-referral law solely to the ''market value'' approach. One commenter asserted that stakeholders should not be restricted to exclusive use of the market approach to value a physician's personal services or promote exclusive use by valuators of physician compensation survey data. Other commenters requested that hospitals should be permitted to use existing written offers to a physician from other similarly situated providers to support a valuation. One of these commenters requested guidance on how fair market value should be determined and documented for timeshare arrangements, citing the ''cost plus'' guidance from Phase I regarding equipment leases as potentially appropriate (66 FR 876 through 877). Another of the commenters asked for additional guidance on recruiting and paying physicians in rural areas, including the use of supply, demand, access, and community need to support the fair market value of a physician's compensation. Another commenter requested that CMS provide additional guidance or examples on what data, facts, and circumstances should be applied to evaluate fair market value. The commenter requested specific guidance on the relevance of payor mix, market supply and demand data, cost of living, physician skills, and experience. A different commenter noted costs of care, costs for medical liability insurance, costs of equipment and staffing, certificate of need laws, and provider and related taxes on health care services and centers as relevant factors when determining the fair market value of compensation.

Response: As discussed above, we are retracting our statements in the proposed rule equating ''general market value'' with the valuation principle of ''market value'' (84 FR 55798). We did not intend to limit the valuation of assets, compensation, or rental property to the market approach or prescribe any other particular method for determining the fair market value and general market value of compensation. As we have stated consistently in prior rulemakings, to establish the fair market value (and general market value) of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions that are not in a position to refer to one another (66 FR 944). We emphasize that our use of the language ''commercially reasonable'' in Phase I (and again in Phase III (72 FR 51015 through 51016)) was also not intended to limit the valuation of assets, compensation, or rental property to a specific valuation approach or prescribe any other particular method for determining the fair market value and general market value of compensation. Rather, as stated in Phase II and reiterated in Phase III, we will consider a range of methods of determining fair market value and that the appropriate method will depend on the nature of the transaction, its location, and other factors (69 FR 16107 and 72 FR 51015 through 51016). We decline to affirm the specific valuation suggestions of the commenters because the amount or type of documentation that will be sufficient to confirm fair market value (and general market value) will vary depending on the circumstances in any given case (66 FR 944), but refer readers to the Phase I rulemaking for an extensive discussion on potentially acceptable valuation methods (66 FR 944 through 945).

Comment: Several commenters expressed appreciation for the examples in the proposed rule regarding when an arrangement may involve compensation above or below what national market data (salary surveys) suggests would be appropriate. The commenters stated that the ability to factor in unique circumstances, such as whether a physician is particularly remarkable in his or her field, will allow entities to design compensation packages that more fully account for the broader circumstances of an arrangement. One commenter emphasized that the analysis of fair market value is always predicated on an analysis of the actual terms of a transaction and the actual facts and circumstances, while another commenter agreed specifically that extenuating circumstances may dictate that parties to an arm's-length transaction veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties. The commenter urged CMS to include this language (or similar language) in regulation text to provide further assurances to stakeholders of CMS' policy. Another commenter requested that we acknowledge that there are other factors that may justify *higher* levels of compensation rates for physician services in markets that may have relatively low cost of living standards due to market supply and demand. A different commenter discussed the difficulty of establishing fair market value in rural areas and

other challenging markets. This commenter noted that, in some instances, a hospital might need to compensate a physician above what is indicated in some published salary schedules in order to convince the physician to relocate to the market area and fill a dire patient need. The commenter was concerned that the example in the proposed rule regarding lower cost of living in certain markets could be read to prohibit compensation above what is found in salary schedules. Some commenters requested additional examples of circumstances that could justify deviating from salary survey data. A few other commenters objected to the examples and disagreed that extenuating circumstances could require a downward deviation from salary surveys.

Response: It appears from the comments that stakeholders may have been under the impression that it is CMS policy that reliance on salary surveys will result, in all cases, in a determination of fair market value for a physician's professional services. It is not CMS policy that salary surveys necessarily provide an accurate determination of fair market value in all cases. However, we decline to include in regulation text, as requested by one of the commenters, a statement that extenuating circumstances may dictate that parties to an arm's-length transaction should veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the transaction when determining the fair market value of the compensation under their transaction. We believe such a statement is unnecessary in light of our policy discussion in the proposed rule and this final rule and our concern that it could reduce the clarity in the definitions of ''fair market value'' and ''general market value'' that we and stakeholders seek.

Consulting salary schedules or other hypothetical data is an appropriate starting point in the determination of fair market value, and in many cases, it may be all that is required. However, we agree with the commenter that asserted that a hospital may find it necessary to pay a physician above what is in the salary schedule, especially where there is a compelling need for the physician's services. For example, in an area that has two interventional cardiologists but no cardiothoracic surgeon who could perform surgery in the event of an emergency during a catheterization, a hospital may need to pay above the amount indicated at a particular percentile in a salary schedule to attract and employ a cardiothoracic surgeon. We also agree with the commenter that emphasized the need for an analysis of the actual terms of a transaction and the actual facts and circumstances of the parties. In our view, each compensation arrangement is different and must be evaluated based on its unique factors. That is not to say that common arrangements, where the services required are identical regardless of the identity of the physician providing them, do not lend themselves well to the use of salary surveys for determining compensation that is fair market value.

Our examples in the proposed rule were intended to show that a variety of factors could affect whether the amount shown in a salary schedule is too high or too low to be fair market value for the services of the subject transaction. In some instances, it is exactly right. Parties do not necessarily fail to satisfy the fair market value requirement simply because the compensation exceeds a particular percentile in a salary schedule; nor are parties required to pay a physician what is shown in a salary schedule if the specific circumstances do not warrant that level of compensation. With respect to the commenters that took issue with the statements in the proposed rule that the fair market value of a particular physician's services may be below what is indicated in a salary schedule, we believe that salary schedules should not be used by a physician to demand compensation that is above what well-informed parties that are not in a position to generate business for each other would agree is the fair market value of the physician's services. We wish to be perfectly clear that nothing in our commentary was intended to imply that an independent valuation is required for all compensation arrangements.

Comment: Two commenters, in identical statements, expressed concern with the proposed definition of ''general market value.'' The commenters contended that, despite the statutory language that fair market value means the value in an arm's-length transaction, consistent with the general market value, there is no reason to believe that the reference to ''general market value'' modifies ''fair market value'' such that fair market value means anything other than what it means to the business valuation profession, and suggested that CMS leave the determination of fair market value to the business valuation profession. These commenters shared a definition of ''fair market value'' found in the International Glossary of Business Valuation Terms, with slight modification to recognize the valuation of services and resources as well as property and goods; specifically, the price, expressed in terms of cash equivalents, at which property, services, and resources would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's-length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts. The commenters asserted that this definition would not require valuators to limit themselves to the market approach or depart from time-honored valuation principles of their profession, including consideration of more than just physician compensation survey data. Ultimately, the commenters requested that CMS not adopt a new definition of ''fair market value'' (with or without a definition of ''general market value'') to take advantage of the consensus reached within the valuation profession.

Response: We decline to retain the current definition of ''fair market value'' (with or without a definition of ''general market value'') as requested by the commenters. First, the term ''general market value'' is included in the statutory definition of ''fair market value'' and we cannot ignore it for purposes of the statutory exceptions or remove it from our regulations. Second, we expect that our retraction of certain statements from the proposed rule and the clarification of previous commentary on valuation methods will assuage the commenters' concerns. As described above, we are finalizing only slight modifications to the existing definitions of ''fair market value'' and ''general market value'' to clearly indicate the statute's specific requirements for determining the fair market value of rental property and to disentangle the volume or value and other business generated standards of the exceptions to the physician self-referral law from the definition of ''general market value.''

Comment: Most commenters supported the reorganization of the definitions, noting that the proposed structure provides better clarity. Some commenters urged CMS to adopt the definitions of ''fair market value'' and ''general market value'' as proposed. The commenters expressed appreciation for the restructuring of the existing definition of ''fair market value'' to extract the separate term ''general market value'' and the link to the volume or value standard. One of the commenters stated that the proposed definition of ''fair market value'' better aligns with the definition set forth in the statute.

Response: We agree that the final structure of the definitions of ''fair market value'' and ''general market value'' is clearer than our existing regulations. As we discussed above and in response to earlier comments, we are finalizing slight modifications to the proposed definitions. We are finalizing our proposal to remove the link to the volume or value standard in the definition of ''general market value'' as requested by the commenters. We believe that structuring the definition of ''fair market value'' to provide for a definition of general application, a definition applicable to the rental of equipment, and a definition applicable to the rental of office space facilitate parties' compliance with the fair market value requirement in the exceptions to the physician self-referral law that apply to the specific type of compensation arrangement between them. Similarly, we believe that definitions of ''general market value'' specific to each of the types of transactions contemplated in the exceptions to the physician self-referral law—asset acquisition, compensation for services, and rental of equipment or office space—will facilitate stakeholders' understanding of the requirements for fair market value compensation that is consistent with the general market value and ease overall compliance efforts.

Comment: A large number of commenters requested that we establish rebuttable presumptions that compensation is fair market value or ''safe harbors'' that would deem compensation to be fair market value if certain conditions are met. The commenters variously suggested that the following should be deemed to be fair market value: Compensation set within a range of percentiles identified in independent salary surveys (with a wider band of permissible compensation for physicians who practice in medically underserved areas, health professional shortage areas, or rural areas), compensation set within the parameters of an independent third-party valuation, and compensation set in accordance with a valuation process that meets certain conditions patterned after those set forth in IRS regulations at 26 CFR 53.4958–6 (related to excess benefit transactions). Some of the commenters asserted that a ''safe harbor'' based on a range of values in salary surveys would be consistent with what they stated was established CMS policy that compensation set at or below the 75th percentile in a salary schedule is appropriate and compensation set above the 75th percentile is suspect, if not presumed inappropriate.

Response: For the reasons explained in Phase I (66 FR 944 through 945), Phase II (69 FR 16092), and Phase III (72 FR 51015), we decline to establish the rebuttable presumptions and ''safe harbors'' requested by the commenters. We are uncertain why the commenters believe that it is CMS policy that compensation set at or below the 75th percentile in a salary schedule is always appropriate, and that compensation set above the 75th percentile is suspect, if not presumed inappropriate. The commenters are incorrect that this is CMS policy.

C. Group Practices (§ 411.352)

In the proposed rule, we proposed certain revisions to the group practice rules at § 411.352 that relate to corresponding proposals regarding the definitions and special rules for ''commercially reasonable'' compensation arrangements, ''fair market value'' compensation, and the volume or value standard applicable throughout the physician self-referral law and regulations (84 FR 55799 through 55802). We also proposed a revision to the rules regarding the distribution of overall profits intended to support our policies related to the transition from a volume-based to a value-based health care system (84 FR 55800 through 55801). We discuss these proposals and our final regulations in section II.C.2. of this final rule.

1. Interpretation of the ''Volume or Value Standard'' for Purposes of the Group Practice Regulations (§ 411.352(g))

As we discussed in the proposed rule, in conjunction with our proposals related to the volume or value standards, we reviewed the physician self-referral regulations to ensure that the standards related to the volume or value of a physician's referrals (the volume or value standard) and the other business generated by the physician (the other business generated standard) are expressed using standardized terminology (84 FR 55799). We identified several occurrences of inconsistent expression of the standards. Although section 1877 of the Act uses more than one phrase to describe the volume or value and other business generated standards, which may be one reason for variations in the regulation text, we believe that the references are all to the same underlying prohibition on compensation that fluctuates with the volume or value of a physician's referrals or the other business generated by a physician for the entity providing the remuneration. Therefore, as discussed in section II.B.3. of this final rule, we proposed and are finalizing conforming changes throughout our regulations to delineate these standards as a prohibition on compensation that *takes into account* the volume or value of a physician's referrals or other business generated by the physician for the entity providing the remuneration. However, because the language in § 411.352(g) and (i) mirrors the statutory language at section 1877(h)(4)(iv) of the Act, we did not propose changes to the ''volume or value'' regulation text in either of those paragraphs. The terms ''based on'' and ''related to'' remain in the regulation text at § 411.352(g) and (i). We are affirming here that we interpret the requirements of § 411.352(g) and (i) to incorporate the volume or value standard as it relates to a physician's referrals; that is, compensation to a physician who is a member of a group practice may not be determined in any manner that takes into account the volume or value of the physician's referrals (except as provided in § 411.352(i)), and profit shares and productivity bonuses paid to a physician in the group may not be determined in any manner that takes into account the volume or value of the physician's referrals (except that a productivity bonus may directly take into account the volume or value of the physician's referrals if the referrals are for services ''incident to'' the physician's personally performed services).

Prior to the revisions we are finalizing in this final rule, the regulation at § 411.352(g) stated that ''[n]o physician who is a member of the group practice directly or indirectly receives compensation *based on* the volume or value of his or her referrals, except as provided in § 411.352(i)'' (emphasis added). We interpret this to mean that, in order to satisfy this requirement for qualification as a ''group practice,'' no physician who is a member of the group practice receives compensation that directly or indirectly *takes into account* the volume or value of his or her referrals (unless permitted under § 411.352(i)). Our interpretation is consistent with the interpretation of ''related to'' set forth in Phase I, where we used the terms ''based on,'' ''related to,'' and ''takes into account'' interchangeably when describing the final group practice regulations (66 FR 908 through 910).

Prior to the revisions we are finalizing in this final rule, the regulation at § 411.352(i) stated that a physician in a group practice may be paid a share of overall profits of the group practice, provided that the share is not

determined in any manner that *is directly related to* the volume or value of referrals by the physician. We have long interpreted ''is directly related to'' the volume or value of referrals to mean ''takes into account'' the volume or value of referrals. In Phase I, we discussed this provision and stated that the Congress expressly limited profit shares for group practice members to methodologies that do not directly *take into account* the member's designated health services referrals, and that, under the statutory scheme, revenues generated by designated health services may be distributed to group practice members and physicians in the group in accordance with methods that indirectly *take into account* referrals (emphasis added) (66 FR 862 and 908).

Despite the varying language of the regulations, as detailed in the proposed rule (84 FR 55800), we consider the regulations at § 411.352(g) and (i) to prohibit compensation to physicians in a group practice that is determined in any manner that takes into account the volume or value of the physician's referrals to the group practice. The new special rule at § 411.354(d)(5) establishes the universe of compensation that we consider to be determined in a manner that takes into account the volume or value of a physician's referrals to the entity paying the compensation. As described in section II.B.3. of this final rule, this special rule applies in all instances where our regulations include the volume or value standard, except as specified in § 411.354(d)(5)(iv). Therefore, with respect to both § 411.352(g) and (i), when determining whether the physician's compensation, share of overall profits, or productivity bonus is based on, is directly or indirectly related to, or takes into account the volume or value of the physician's referrals to the group practice, the special rule at final § 411.354(d)(5) applies.

We received the following general comment and our response follows.

Comment: Some commenters argued that we should not finalize our proposals because group practices need the utmost flexibility to participate and succeed in value-based health care delivery and payment systems.

Response: Nothing in our final regulations prohibits a group practice (or any physician practice) that furnishes designated health services and the physicians who are owners, employees, or independent contractors of the practice from qualifying as a value-based enterprise. The new exceptions at § 411.357(aa)(3) may be available to such an enterprise, assuming it meets all the requirements of the definitions and exceptions. Those exceptions do not include fair market value or volume or value requirements. The regulations at § 411.352 apply to group practices that operate in a FFS payment environment. We do not agree that our final regulations at § 411.352 will prohibit a group practice from participating and succeeding in a value-based health care delivery and payment system.

2. Special Rules for Profit Shares and Productivity Bonuses (§ 411.352(i))

a. Distribution of Profits Related to Participation in a Value-Based Enterprise

We proposed a new § 411.352(i)(3) to address downstream compensation that derives from payments made to a group practice, rather than payments made directly to a physician in the group, that relate to the physician's participation in a value-based arrangement. Certain downstream distribution arrangements are currently protected under waivers in the Shared Savings Program and certain Innovation Center models. However, outside of the Shared Savings Program or an Innovation Center model, profit shares or productivity bonuses paid to a physician in a group practice that are determined in any manner that directly takes into account the volume or value of his or her referrals to the group practice are strictly prohibited by the physician self-referral statute and regulations.

The special rules for the profit shares and productivity bonuses paid to physicians in a group practice prohibit calculation methodologies that *directly* take into account the volume or value of the recipient physician's referrals to the group practice. Thus, by way of example, in a 100-physician group practice where only two of the physicians participate with a hospital as a value-based enterprise in a commercial payor-sponsored alternative payment model, the profits from the designated health services ordered by the physicians and furnished by the group practice to beneficiaries assigned to the model may not be allocated directly to the two physicians. We explained in the proposed rule that commenters on the CMS RFI interpreted this to mean that the special rules at § 411.352(i) would restrict the group practice to allocating alternative payment model-derived income that includes revenues from designated health services among all physicians in the group (or a component of at least five physicians in the group) in order to ensure that such income is allocated in a manner that only *indirectly* takes into account the volume or value of the two physicians' referrals. The commenters suggested that this restriction discourages physician participation in alternative payment or other value-based care models because physicians cannot be suitably rewarded for their accomplishments in advancing the goals of the model, which is at odds with the Secretary's vision for achieving value-based transformation by pioneering bold new payment models. We also described the assertion of another commenter on the CMS RFI that, because physician decisions drive the overwhelming majority of all health care spending and patient outcomes, it is not possible to transform health care without the participation of physicians in value-based health care delivery and payment models with other health care providers. We stated that we share the commenters' concerns regarding physician participation in value-based health care delivery and payment models and are also concerned that our regulations could undermine the success of the Regulatory Sprint or the larger transition to a value-based health care system. Therefore, we proposed changes to § 411.352(i) with respect to the payment of profit shares to eliminate this potential barrier to robust physician participation in value-based care delivery (84 FR 55800). We are finalizing our proposal with modifications to the regulation text as proposed. As explained in our responses to comments below, the policy will be codified at revised § 411.352(i)(3) and effective on January 1, 2022.

For the reasons described elsewhere in this final rule, in the exceptions for value-based arrangements at new § 411.357(aa), we did not propose to prohibit remuneration that takes into account the volume or value of a physician's referrals. The revisions finalized at § 411.352(i)(3) are an extension of this policy. Specifically, we are finalizing a provision related to the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise. Under our final policy at § 411.352(i)(3), such profits may be distributed to the participating physician and will not be considered to directly relate to (or take into account) the volume or value of the physician's referrals. In other words, a group practice may distribute directly to a physician in the group the profits from designated health services furnished by the group that are derived from the

physician's participation in a value-based enterprise, including profits from designated health services referred by the physician, and such remuneration will be deemed not to be based on (or take into account) the volume or value of the physician's referrals. The regulation finalized at § 411.352(i)(3) would permit the 100-physician group practice in the previous example to distribute the profits from designated health services derived from the two physicians' participation in value-based enterprise directly to those physicians. Physician #1 could receive a profit distribution that considers his or her referrals to the group that are directly attributable to his or her participation in the value-based enterprise (and its corresponding participation in the model), and Physician #2 could receive a profit distribution that considers his or her referrals to the group that are directly attributable to his or her participation in the value-based enterprise (and its corresponding participation in the model). Neither distribution would jeopardize the group's ability to qualify as a ''group practice'' under § 411.352. In the proposed rule, we sought comment regarding whether we should permit the distribution of ''revenue'' from designated health services, as opposed to ''profits'' from designated health services in order to effectuate the goals described elsewhere in the proposed rule (84 FR 55801) and this final rule. As explained in our responses to comments below, we are finalizing our proposal to apply the rule at final § 411.352(i)(3) to ''profits'' from designated health services, which will be effective on January 1, 2022.

We received the following comments and our responses follow.

Comment: Commenters widely supported our proposal to address the distribution of profits from designated health services that are derived from the participation in a value-based enterprise by a physician in a group practice. Commenters urged us to finalize our proposal to permit the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise without having to aggregate the profits with the overall profits of the group practice or a component of five physicians within the group practice. Commenters asserted that this flexibility will encourage physicians to incorporate value-based elements into their practices, as well as physician participation in value-based enterprises on an individual basis and in circumstances where the entire group practice's participation may not be warranted or desirable.

Response: We agree with the commenters regarding the potential impact of the permitted distributions; namely, that individual physicians in a group practice may be encouraged to participate in a value-based enterprise with providers and suppliers outside of the physician's own group practice even when the group practice does not participate as a whole in the value-based enterprise. We believe that the protection afforded by the safeguards in the new definitions and exceptions related to value-based care delivery and payment will ensure that distribution of profits to an individual physician (or subset of physicians) within a group practice should not increase the risk of inappropriate utilization of designated health services or program or patient abuse.

Comment: One commenter noted that proposed § 411.352(i)(3) was not structured in the same way as the ''special rules'' for distribution of overall profits and payment of productivity bonuses. The commenter expressed concern that the proposed regulation text would not create the deeming provision we intended. The commenter requested that we revise the regulation to expressly state that, where a group practice's profits from designated health services are directly attributable to a physician's participation in a value-based enterprise and those profits are distributed to the physician, the compensation to the physician is deemed not to take into account the volume or value of the physician's referrals under § 411.352(g). The commenter asserted that making these revisions would eliminate any inference that § 411.352(i)(3) is not an exception to § 411.352(g).

Response: The commenter is correct about the structure of the three provisions in § 411.352(i) that describe methodologies for the distribution of profits from designated health services and the payment of productivity bonuses. We agree that standard language and further clarification of the provision at § 411.352(i)(3) is warranted to ensure the provision operates as a deeming provision as we intend. We have revised the final regulation accordingly. Specifically, final § 411.352(i)(3) provides that notwithstanding paragraph (g) of § 411.352, profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined at § 411.351, may be distributed to the participating physician.

Comment: With respect to our proposal to permit the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, we sought comment regarding whether we should permit the distribution of ''revenue'' from designated health services, as opposed to ''profits'' from designated health services in order to effectuate the goals described elsewhere in the proposed rule and this final rule. One commenter stated that the furnishing of certain designated health services does not always result in profit for the group practice and suggested that permitting the distribution of revenue from designated health services would provide needed flexibility to encourage physicians to participate in value-based care delivery. Another commenter suggested that we permit the distribution of revenue from designated health services to simplify the regulation because revenues are easier to calculate than profits.

Response: We have no reason to doubt the commenter's assertion that a group practice does not realize a profit on every designated health service that it furnishes. Thus, it is possible that a group practice could have no profits to distribute to a physician in the group who makes a referral of designated health services for a patient in the target patient population while undertaking value-based activities as a VBE participant in a value-based enterprise. Although it may be true that it is easier to calculate revenues than to calculate profits, in general, we believe that a group practice's distribution of revenues to a referring physician rather than profits, which are calculated by deducting the expenses incurred in furnishing the designated health service, could serve as an inducement to make additional and potentially inappropriate referrals to the group practice. This is consistent with our statement in the 1998 proposed rule that rewarding a physician each time he or she self-refers for a designated health service can constitute an incentive to overutilize services (63 FR 1691). We are unclear how the sharing of a group practice's revenues with a physician would encourage the physician's participation in value-based care delivery or how the physician's participation in his or her individual capacity in a value-based enterprise would mitigate our concerns regarding the inducement to refer any of the physician's patients outside the target patient population for designated health services furnished by the group practice. We are not adopting the

commenters' recommendation to permit the distribution of revenues from designated health services that are directly attributable to a physician's participation in a value-based enterprise.

b. Clarifying Revisions

(1) Restructuring of the Regulation at § 411.352(i)

We proposed to restructure and renumber § 411.352(i) as well as clarify several provisions of the regulation. As we stated in the proposed rule, we believe that the revisions will enable groups to determine with more certainty whether compensation paid to a physician in the group as profit shares or productivity bonuses takes into account the volume or value of referrals and, if it does, whether there is a direct or indirect connection to the volume or value of the physician's referrals (84 FR 55801). Except as noted above with respect to the uniformity of the structure of the provisions in § 411.352(i), we received no comments on the general restructuring of the regulations, and are finalizing our proposal to restructure and renumber the regulations at § 411.352(i) without modification to the proposed numbering and headers of the regulation. Our purpose in restructuring the regulation is to more closely adhere to the structure of section 1877(h)(4)(B) of the Act and to express in affirmative language which profit shares and productivity bonuses are permissible; that is, permitting the payment of a profit share or productivity bonus that does not directly take into account the volume or value of referrals is the affirmative and more simple way of saying, as our current regulations do, that the profit share or productivity bonus is permissible but only if it does not directly take into account the volume or value of referrals. In addition, the special rules for profit shares and productivity bonuses, as finalized, follow the format of our special rules on compensation at § 411.354(d) and our special rules for compensation arrangements at § 411.354(e). As stated in the proposed rule, our addition of introductory language at § 411.352(i) and revised language at § 411.352(i)(1) and 411.352(i)(2) do not constitute a substantive change to the noted provisions (84 FR 55801).

(2) Overall Profits

We proposed revisions to clarify our interpretation of the overall profits of a group that can be distributed to physicians in the group. Until now, the term ''overall profits'' was defined to mean two different things: (1) The group's entire profits derived from designated health services; and (2) the profits derived from designated health services of any component of the group practice that consists of at least five physicians. As stated in the proposed rule, stakeholders informed us that they were confused about the definition. For example, stakeholders informally inquired whether the profits of a group practice that has only two, three, or four physicians may be distributed at all. We proposed to revise the definition of ''overall profits'' to mean the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. To further clarify this definition, we proposed regulation text at revised § 411.352(i)(1)(ii) stating that, if there are fewer than five physicians in the group, ''overall profits'' means the profits derived from all the designated health services of the group. We stated that we believe that this more precisely states the policy articulated in Phase I (66 FR 909 through 910). For the reasons explained in our responses to comments, we are finalizing the definition of ''overall profits'' at § 411.352(i)(1)(ii) as proposed.

We highlight that the final regulation at § 411.352(i)(1)(ii) includes the words ''all the'' before ''designated health services.'' As we stated in the proposed rule, stakeholders' informal inquiries regarding the permissible methods of distributing profits from designated health services indicated that the regulation text may not have precisely evidenced our intent (84 FR 55801). Such inquiries included whether it is permissible to distribute profit shares of only some types of designated health services provided by a group practice without distributing the profits from the other types of designated health services provided by the group practice, and whether a group practice may share profits from one type of designated health service with a subset of physicians in a group practice and the profits from another type of designated health service with a different (possibly overlapping) subset of physicians in the group practice. As discussed, we are finalizing at § 411.352(i)(1)(ii) that overall profits means ''the profits derived from all the designated health services.'' Thus, the profits from all the designated health services of any component of the group that consists of at least five physicians (which may include all physicians in the group) must be aggregated before distribution. Under this final rule, a physician practice that wishes to qualify as a group practice may not distribute profits from designated health services on a service-by-service basis. To illustrate, suppose a physician practice provides both clinical laboratory services and diagnostic imaging services—both designated health services—to its patients in a centralized building (as defined at § 411.351) or a location that qualifies as a ''same building'' under § 411.351 and meets the requirements at § 411.355(b)(2)(i). If the practice wishes to qualify as a group practice, it may not distribute the profits from clinical laboratory services to one subset of its physicians and distribute the profits from diagnostic imaging to a different subset of its physicians.

We are cognizant that, under the requirement at § 411.352(e), to qualify as a ''group practice,'' the overhead expenses of, and income from, a practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Essentially, a group practice's compensation methodology must be established prospectively. Based on the comments, it is our understanding that group practice physician compensation methodologies are often established prior to the beginning of a calendar year. We are concerned that the regulations we are finalizing in this final rule may require group practices that relied on their interpretation of § 411.352(i) (as it existed prior to this final rule) to adjust their compensation methodologies and, if so, they may not have sufficient time prior to the end of the current calendar year to make necessary adjustments to their compensation methodologies. As explained in our responses to comments below, we are delaying the effective date of revised § 411.352(i)(1) until January 1, 2022. Through December 31, 2021, the definition of ''overall profits'' will be as set forth at existing § 411.352(i)(2).

We also proposed to remove the reference to Medicaid from the definition of ''overall profits.'' We believe that the inclusion of this reference unnecessarily complicates the regulation. In the proposed rule, we noted that it is possible that the reference to designated health services payable by Medicaid is related to the definition of ''referral'' in the 1998 proposed rule (63 FR 1692). There, with respect to the definition of group practice, we stated that, because of our interpretation of what constitutes a ''referral,'' an entity wishing to be considered a group practice in order to use the in-office ancillary services exception may not compensate its members based on the volume or value

of referrals for designated health services for Medicare or Medicaid patients but could do so in the case of other patients (63 FR 1690). However, when the 1998 proposed policies were finalized, the definition of ''referral'' omitted all references to Medicaid. Nonetheless, the reference to Medicaid in final § 411.352(i)(2), which was also proposed in the 1998 proposed rule (as a definition in § 411.351), was not congruently omitted when finalized. We explained further in the proposed rule that, under the definition of ''designated health services'' at § 411.351, ''designated health services payable by . . . Medicaid'' would not include any services. This is because the definition of ''designated health services'' includes only those services payable in whole or in part by Medicare. Although the qualifying language in this definition potentially allows for a different definition ''as otherwise noted in this subpart,'' the regulations at existing § 411.352(i)(2) do not expressly articulate an alternative definition for ''designated health services.'' Rather, they simply state that the overall profits of a group include profits derived from designated health services payable by Medicare *or Medicaid.* For consistency with the definitions and regulations we proposed (and are finalizing here), we proposed to eliminate the references to Medicaid in the definition of ''overall profits.'' We are finalizing our proposal. However, as explained in our responses to comments below, we are delaying the effective date of these updates until January 1, 2022 to coincide with the effective date of the other revisions to the definition of ''overall profits.''

Our group practice regulations also articulate the general rule that overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of designated health services. In this final rule, we are finalizing our proposal to move the prefatory language of this requirement from existing § 411.352(i)(2) to revised § 411.352(i)(1)(iii) without substantive change. We are also finalizing our proposal to replace the varying language in the methods deemed not to relate directly to the volume or value of referrals (the deeming provisions). One of the current deeming provisions references ''the group's profits'' and another references ''revenues'' where both should reference ''overall profits.'' We are finalizing the revision to use the term ''overall profits'' in both of these deeming provisions in order to articulate more clearly that the deeming provisions relate to methods for distributing a share of overall profits, not ''profits'' or ''revenues.'' To avoid complications associated with the restructuring of § 411.352(i), as explained in our responses to comments below, we are delaying the effective date of these updates until January 1, 2022 to coincide with the effective date of the revised definition of ''overall profits.''

We also proposed to revise the language related to one of the deemed permissible methods for distributing shares of overall profits by replacing ''are not [designated health services] payable by any Federal health care program or private [payor]'' with ''and would not be considered designated health services if they were payable by Medicare.'' This change is reflected in revised § 411.352(i)(1)(iii)(B). Current regulations provide that a share of overall profits will be deemed not to directly take into account the volume or value of referrals if revenues derived from designated health services are distributed based on the distribution of the group practice's revenues attributed to services that are not designated health services payable by ''any Federal health care program or private payer.'' As we explained in the proposed rule, the definition of ''designated health services'' includes only those specified services that are payable by Medicare (84 FR 55802). Thus, we believe a better way to reflect our policy that overall profits may be distributed based on the distribution of the group practice's revenues from services other than those in the categories of services that are ''designated health services'' is to deem the payment of a share of overall profits not to directly take into account the volume or value of a physician's referrals if overall profits are distributed based on the distribution of the group's revenues attributed to services that are not designated health services *and would not be considered designated health services if they were payable by Medicare.* We proposed to revise the regulation in this manner and renumber current § 411.352(i)(2)(ii) to § 411.352(i)(1)(iii)(B). We are finalizing this proposal. As noted, to avoid complications associated with the restructuring of § 411.352(i), as explained in our responses to comments below, we are delaying the effective date of these updates until January 1, 2022 to coincide with the effective date of the revised definition of ''overall profits.''

Lastly, we did not propose to revise the third deeming provision to replace the term ''revenues'' with ''overall profits.'' The third deeming provision states that a share of overall profits will be deemed not to relate directly to the volume or value of referrals if revenues derived from designated health services constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group. We did, however, propose nonsubstantive updates to the language used in this deeming provision and we are finalizing those nonsubstantive changes. Final § 411.352(i)(1)(iii)(C) deems as a permissible methodology for distributing overall profits a methodology under which revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group. Again, to avoid complications associated with the restructuring of § 411.352(i), as explained in our responses to comments below, we are delaying the effective date of these updates until January 1, 2022 to coincide with the effective date of the revised definition of ''overall profits.''

We received the following comments and our responses follow.

Comment: One commenter characterized our policy clarifications as an attempt to micromanage the organization, governance, and operation of group practices. The commenter opposed any revisions to the group practice regulations (except for the addition of new § 411.352(i)(3), which the commenter found beneficial for group practices). The commenter asserted that we should not finalize the revisions to § 411.352(i)(1) because the statute is not prescriptive with respect to what methodologies are permissible for distributing overall profits to physicians. Another commenter asserted that we gave no rationale to support our interpretation of the statutory term ''overall profits'' as meaning profits from all the designated health services of a group practice or a component of at least five physicians in the group practice (which may include all physicians in the group practice).

Response: The commenter is correct that section 1877(h)(4)(B) of the Act does not prescribe the methodology that a group practice may use to pay shares of its overall profits, provided that the share is not determined in any manner that is directly related to the volume or value of referrals by the physician to whom the share is paid. The commenter appears to confuse our proposal to clarify our interpretation of the term ''overall profits'' as used in section 1877(h)(4)(B) of the Act with a proposal

to limit payment methodologies, although our final regulations may indeed result in some group practices modifying their physician compensation with respect to payment of shares of overall profits from designated health services.

We have long interpreted the term ''overall profits'' as the profits from the group practice's overall pooled revenues from designated health services (63 FR 1691). In the 1998 proposed rule, we stated that we regard ''overall profits of the group'' to mean all of the profits a group can distribute in any form to physicians in the group, even if the group is located in two different states or has many different locations within one state, and that we would not interpret ''overall profits'' as the profits that belong only to a particular specialty or subspecialty group (63 FR 1691). When finalizing our proposals related to the payment of shares of overall profits in Phase I, we stated that the Congress recognized that, in the case of group practices, revenues derived from designated health services must be distributed to the group practice physicians in some fashion, even though the physicians generate the revenue (66 FR 876). However, because the Congress wished to minimize the economic incentives to generate unnecessary referrals for designated health services, section 1877(h)(4)(B) of the Act permits a physician in the group practice to receive a share of the overall profits of the group practice, provided that the share is not determined in any manner that is directly related to the volume or value of referrals by the physician. We described our proposals in the 1998 proposed rule as requiring that profits must be aggregated at the group level and not at a component level (66 FR 908). In Phase I, we defined ''share of overall profits'' to mean a share of the *entire* profits of the *entire* group (or any component of the group that consists of at least five physicians) derived from designated health services (66 FR 908) (emphasis added). We stated that overall profit shares must be derived from aggregations of the entire practice or a component of the practice consisting of at least five physicians (66 FR 907). The regulation text defining ''overall profits'' finalized in Phase I stated that overall profits means the group's entire profits derived from ''DHS'' payable by Medicare or Medicaid or the profits derived from ''DHS'' payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. The regulation text does not accord precisely with our preamble guidance that states that overall profits means the entire profits of the entire group. It has not been revised until now.

We note that, in § 411.351, the regulation text provides a definition for ''designated health services (DHS).'' The definition states that DHS means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in § 411.351, and lists the various individual categories of services that are considered designated health services. Stakeholders may have evaluated this portion of the definition of ''designated health services'' within the context of the definition of ''overall profits'' and interpreted ''overall profits'' to mean the group's entire profits from any one of the individual categories of designated health services identified in the definition at § 411.351. This was not our intention when using the acronym ''DHS'' in the definition of ''overall profits'' in the regulation text at § 411.352(i).

We are finalizing our proposal to clarify our longstanding interpretation of the term ''overall profits'' as used in section 1877(h)(4)(B) of the Act at final § 411.352(i)(1)(ii). However, because the regulation text at § 411.352(i) has not fully and exactly depicted the policy set forth in our Phase I preamble guidance, we are making the revisions prospective. In addition, for the reasons set forth in the response to comments below, we are delaying the effective date of the revisions to § 411.352(i) until January 1, 2022.

Comment: Some commenters opposed our proposal to define ''overall profits'' to mean the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group, asserting that group practices should be able to distribute profits of some types of designated health services, but not others. Other commenters asked for clarification regarding whether a group practice could retain its profits (from designated health services or otherwise), or whether our revisions would require a group practice to distribute all of its profits to physicians in the group in order to qualify as a group practice.

Response: Nothing in final § 411.352(i)(1)(ii) (or any other physician self-referral regulation) requires the distribution of a group practice's profits from designated health services. However, if a group practice wishes to pay shares of overall profits to any of its physicians, it must first aggregate: (1) The entire profits from the entire group; or (2) the entire profits from any component of the group that consists of at least five physicians. Once aggregated, the group practice may choose to retain some of the profits or distribute all of the profits through shares of overall profits paid to its physicians. A group practice need not treat all components of at least five physicians the same with respect to the distribution of shares of overall profits from designated health services. That is, the group practice may choose to distribute all of the overall profits from designated health services of one of its components of five physicians to the physicians in that component, and choose to retain some or all of the overall profits from designated health services of another of its components of five physicians. Moreover, we are aware that group practices may utilize eligibility standards to determine whether a physician is eligible for a profit share, such as length of time with the group practice, whether the physician is an owner, employee, or independent contractor of the group practice, or the amount of time that the physician practices (for example, full-time or part-time). Nothing in our regulations prohibits the use of eligibility standards, provided that they do not result in the payment of a profit share that is determined in a manner that is directly related to the volume or value of a physician's referrals. In sum, a group practice may determine for itself how much of the aggregate overall profits it chooses to share with its physicians and which physicians are entitled to a share of the group practice's overall profits; however, all payments of shares of overall profits must comply with the requirements of § 411.352(g) and (i).

Comment: A number of commenters opposed our proposal to define ''overall profits'' from designated health services to mean the profits from all the designated health services of the group practice (or a component of the group that consists of at least five physicians), asserting that group practices should be permitted to distribute the profits from designated health services on a service-by-service basis, which some of the commenters referred to as ''split pooling.'' These commenters variously stated that service-by-service profit shares would allow physicians to receive profits shares more closely related to the services they referred, their specialty, the services they provide, or the expenses they have personally incurred. One of the commenters explained that, for large or multispecialty group practices, in particular, different practice locations or specialties commonly use ancillary

designated health services to varying degrees in connection with the delivery of care in their location or specialty, and another stated that the proposed ''limits'' may inadvertently penalize the ''practices'' within a group that are more profitable due to efficiency and reward those that are less efficient. Another of the commenters asserted that a service-by-service allocation methodology aligns compensation with the physicians who are furnishing professional services in conjunction with designated health services and incurring the related expenses. The commenter complained that not allowing what it referred to as ''pooling by designated health service,'' physicians who have no treatment involvement in the designated health services are nonetheless rewarded financially. A different commenter gave the example of a subset of physicians within a group practice that agree to assume all of the costs of expensive diagnostic testing equipment when there is a dispute within the group as to whether to purchase the equipment. The commenter asserted that service-by-service distribution of profits is appropriate so that the physicians who bear the cost of the equipment also receive the profits arising from the use of the equipment. One commenter stated that distributing profits from designated health services on a service-by-service basis is not an issue, but offered no reason why this is the case. In contrast, several commenters commended CMS for proposing the clarifying language at § 411.352(i)(1)(ii) and supported finalizing the regulatory revisions.

Response: Section 1877(h)(4)(B) of the Act permits a group practice to pay a physician in the group practice a share of overall profits of the group. In Phase I, we shared our interpretation that the term ''overall profits'' means the *entire* profits of the *entire* group (or any component of the group that consists of at least five physicians) derived from designated health services (66 FR 908) (emphasis added). The proposed revisions at § 411.352(i)(1)(ii), which we are finalizing in this final rule, incorporate this long-held interpretation. Commenters provided no justification for their preferred interpretation of the statutory term ''overall profits''—which makes no reference to designated health services as the services that generated the profits—as meaning the profits from any one type of designated health service.

We remind readers that, in order to qualify as a group practice, a physician practice must meet all the requirements set forth in § 411.352. These include that the practice is a unified business with centralized decision making by a body representative of the practice that maintains effective control over the practice's assets and liabilities (including, but not limited to, budgets, compensation, and salaries) and consolidated billing, accounting, and financial reporting. In addition, revenues from patient care services must be treated as receipts of the practice. Certain of the justifications for the commenters' assertions that we should permit a group practice to share the profits from designated health services on a service-by-service basis call into question whether a physician practice that operates as described in the comments could satisfy the unified business test at § 411.352(f) or, potentially, whether the revenues from patient care services are treated as receipts of the practice, as required at § 411.352(d)(1).

As we stated in Phase I, the Congress intended to confer group practice status on *bona fide* group practices and not on loose confederations of physicians who come together substantially in order to capture the profits from referrals of designated health services protected under the exception for in-office ancillary services (66 FR 875). For that reason, we established the unified business test at § 411.352(f). To meet the unified business test, a group practice must be organized and operated on a *bona fide* basis as a single integrated business enterprise with legal and organizational integration (66 FR 906). We designed the group practice rules at § 411.352 to preclude group practice status for loose confederations of physicians that are group practices in name, but not operation. In Phase I, in response to a comment on our 1998 proposed rule, we stated that we generally agree that a group practice should consist of a single medical business whose equity holders operate as a single business by sharing such things as contracts, liability, facilities, equipment, support personnel, management, and a pension plan, and that this aspect of a group practice is addressed by the unified business test at § 411.352(f) (66 FR 898). The essential elements of a unified business are: (1) Centralized decision making by a body representative of the practice that maintains effective control over the group's assets and liabilities (including budgets, compensation, and salaries); and (2) consolidated billing, accounting, and financial reporting. As we stated in Phase I, group practices may distribute the revenues from services that are not designated health services in any manner they wish. The unified business test permits group practices to use cost- and location-based accounting with respect to services that are not designated health services, and, in some cases, with respect to services that are designated health services if the compensation method is not directly related to the volume or value of the physician's referrals and other conditions are satisfied (66 FR 895). However, if a physician practice's payment methods do not indicate a unified business (or indicate a business that is unified solely with respect to the provision of designated health services), the physician practice may not qualify as a group practice under section 1877(h)(4) of the Act and § 411.352 (66 FR 907).

With respect to the specific comments regarding the need for the payment of profit shares on a service-by-service basis, we assume the reference to ''practices'' within a group practice pertains to specialties or locations of the group practice. We remind parties that, if a ''practice'' within a group practice is comprised of five or more physicians, the group practice may aggregate the profits from all the designated health services of the component and pay shares of the overall profits to the physicians in the component, provided that the group practice satisfies all the requirements of § 411.352, including § 411.352(g) and (i). If a ''practice'' within a group practice is not comprised of at least five physicians, the group practice would have to include additional physicians in the component and aggregate the profits from all the designated health services of the component.

Comment: One commenter stated that disparate state certificate of need and self-referral laws result in a patchwork of permitted and prohibited designated health services within different segments or practice locations of the same group practice. The commenter suggested that requiring group practices that operate in multiple states to aggregate all their profits from designated health services will be challenging, but did not elaborate on what those challenges are.

Response: Group practices may use the ''component of five'' rule to aggregate and distribute profit shares. We think that most large group practices, including those that operate in more than one state, will be able to use the component of five rule to establish workable profit distribution methodologies to address issues related to the distribution of profits from designated health services for which all physicians in the group do not make

referrals and discrepancies in the types of designated health services furnished among practice locations due to state certificate of need and self-referral laws.

Comment: Some of the commenters that objected to the proposed revisions to the group practice rules regarding the distribution of shares of overall profits noted that our proposals, if finalized, would require changes to the internal compensation practices in many medical groups. Some of these commenters requested that, if we finalize the proposed changes to the regulation text, we provide a sufficient timeframe of at least one year for all group practices to revise their compensation methodologies. Another commenter was generally supportive of the revisions to § 411.352(i), but expressed concern about the time and effort involved in revising compensation arrangements for group practices that have separated profits by service type until now.

Response: We agree with the commenters that parties may need time to revise compensation methodologies and arrangements for group practice physicians. For that reason, we are delaying the effective date of final § 411.352(i)(1) until January 1, 2022. We believe this will provide group practices sufficient time to evaluate their current compensation methodologies for compliance with final § 411.352(i)(1) and make necessary revisions. Through December 31, 2021, the definition of ''overall profits'' will be as set forth at existing § 411.352(i)(2). We note that the delayed effective date applies to all revisions at final § 411.352(i)(1), including the removal of the reference to ''Medicaid.'' Also, to avoid complications associated with the restructuring of § 411.352(i), we are also delaying the effective date of final § 411.352(i)(2) and (4) to coincide with the effective date of the revised definition of ''overall profits.''

Comment: One commenter was concerned that new § 411.352(i)(3) would negatively impact physicians who are employees or independent contractors of a group practice, noting that only group practice owners are able to share in the group's profits.

Response: The commenter is mistaken. Nothing in section 1877 of the Act or our physician self-referral regulations limits the payment of a share of overall profits to owners of a group practice. Under section 1877(h)(4)(B) of the Act and our regulations, any physician in the group may be paid a share of overall profits of the group practice.

Comment: One commenter requested confirmation that a group practice may designate more than one component of at least five physicians for the allocation of overall profits from designated health services as long as the profits from all the designated health services referred by the physicians in a component are aggregated and the profits shared with the physicians in that component. The commenter also sought confirmation that the various components could be established by grouping together physicians of the same specialty or by any other pooling mechanism, as long as each component consists of at least five physicians.

Response: A group practice may designate more than one component of at least five physicians for the allocation of overall profits from designated health services as long as the profits from all the designated health services referred by the physicians in a component are aggregated and the profits shared with the physicians in that component. Provided that the share of overall profits received by a physician is not determined in any manner that is directly related to the volume or value of the physician's referrals, a group may establish components of at least five physicians by including physicians with similar practice patterns, who practice in the same location, with similar years of experience, with similar tenure with the group practice, or who meet other criteria determined by the group practice. We continue to believe, as we stated in Phase I, that a threshold of at least five physicians is likely to be broad enough to attenuate the ties between compensation and referrals of designated health services (66 FR 909).

Comment: Some commenters asked whether a group practice must use a single methodology for distributing the shares of overall profits attributable to each of its designated components of five physicians. In other words, if a group practice has three designated ''pools'' of at least five physicians (components A, B, and C), must the group practice use the same methodology for distributing the profits for components A, B, and C? The commenters referenced the example in the proposed rule where we stated that a group practice may not distribute the profits from clinical laboratory services to one subset of its physicians or using a particular methodology and distribute the profits from diagnostic imaging to a different subset of physicians (or the same subset of its physicians but using a different methodology) (84 FR 55801).

Response: The example provided in the proposed rule was intended to illustrate the application of the policy that does not permit service-by-service distribution of profits from designated health services (which one of the commenters referred to as ''split pooling''). However, as noted by the commenters, the statement could appear to prohibit the use of different distribution methodologies for different components of five physicians in a group practice. To the extent that parties understood this to be our policy and an indication of how we would interpret the regulations, we are clarifying that a group practice may utilize different distribution methodologies to distribute shares of the overall profits from all the designated health services of each of its components of at least five physicians, provided that the distribution to any physician is not directly related to the volume or value of the physician's referrals. To illustrate, assume a group practice comprised of 15 physicians furnishes clinical laboratory services, diagnostic imaging services, and radiation oncology services. Assume further that the group practice has divided its physicians into three components of five physicians (component A, component B, and component C) for purposes of distributing the overall profits from the designated services of the group practice. Under the final regulations, for each component, the group practice must aggregate the profits from all the designated health services furnished by the group and referred by any of the five physicians in the component. The group practice may distribute the overall profits from all the designated health services of component A using one methodology (for example, a per-capita distribution methodology), distribute the overall profits from all the designated health services of component B using a different methodology (for example, a personal productivity methodology in compliance with § 411.352(i)(1)(iii)(B)), and distribute the overall profits from all the designated health services of component C using a third methodology that does not directly relate to the volume or value of the component physicians' referrals (or the methodology used for component A or B). However, a group practice must utilize the same methodology for distributing overall profits for every physician in the component. That is, using the illustration above, the group practice must use the per-capita distribution methodology for each physician in component A, the personal productivity methodology for each physician in component B, and the same methodology (whichever it utilizes) for each physician in component C. As described in our responses to other comments in this

section II.C.2.b., the group practice could not use different methodologies to distribute the profits of the different types of designated health services within a component.

Comment: Most commenters that commented on our proposals to revise the group practice regulations supported the removal of the reference to Medicaid from the definition of ''overall profits'' and the clarifying discussion in the proposed rule.

Response: As stated above, we are finalizing our proposal to revise § 411.352(i). However, we are delaying the effective date of these updates until January 1, 2022 to coincide with the effective date of the other revisions to the definition of ''overall profits.''

(3) Productivity Bonuses

For consistency with the regulations related to the payment of a share of overall profits, we proposed to revise the introductory language in the deeming provisions for productivity bonuses at renumbered § 411.352(i)(2)(ii) to state that a productivity bonus must be calculated in a reasonable and verifiable manner. We also proposed to renumber the regulation that lists the deeming provisions related to the payment of productivity bonuses from § 411.352(i)(3) to § 411.352(i)(2) and proposed minor changes to the deeming provisions themselves. In addition, we proposed to update the language of existing § 411.352(i)(1) (relocated to § 411.352(i)(2)(i)) to remove ''or both'' as unnecessary because the word ''or'' is interpreted to mean the conjunctive ''and'' as well as the disjunctive ''or.'' We stated that groups may continue to pay a productivity bonus based on services that the physician has personally performed, or services ''incident to'' such personally performed services, or both, provided that the bonus does not directly take into account the volume or value of the physician's referrals (except that the bonus may directly take into account the volume or value of referrals by the physician if the referrals are for services ''incident to'' the physician's personally performed services).

To correct a misstatement about the nature of § 414.22 of this chapter included in existing § 411.352(i)(3)(i), we proposed to revise the deeming provision related to the physician's total patient encounters or relative value units to state that a productivity bonus will be deemed not to relate directly to the volume or value of a physician's referrals if it is based on the physician's total patient encounters or the relative value units personally performed by the physician. We sought comment in the proposed rule regarding whether this provision should limit the methodology to physician work relative value units as defined at § 414.22(a) or whether any personally-performed relative value units should be an acceptable basis for calculating a productivity bonus that is deemed not to relate directly to (that is, directly take into account) the volume or value of referrals. The regulation that deems a productivity bonus not to directly take into account the volume or value of a physician's referrals under certain circumstances includes a provision similar to that at final § 411.352(i)(1)(iii)(B). Therefore, we proposed corresponding revisions at § 411.352(i)(2)(ii)(B) (to be renumbered from current § 411.352(i)(3)(ii)) that would deem the payment of a productivity bonus not to directly relate to (or, as explained in this section II.C.2.b(1), take into account) the volume or value of a physician's referrals if the services on which the productivity bonus is based are not revenues derived from designated health services and would not be considered designated health services if they were payable by Medicare. Finally, we proposed to replace the term ''allocated'' with ''distributed'' at (redesignated) § 411.352(i)(1)(iii)(C) as the latter term reflects the actual payment of the profit share (84 FR 55802). We are finalizing all of our proposals related to the payment of productivity bonuses by a group practice. However, to avoid complications associated with the restructuring of § 411.352(i), as explained in our responses to comments below, we are delaying the effective date of these updates at final § 411.352(i)(2) until January 1, 2022 to coincide with the effective date of the revised definition of ''overall profits.''

We received the following comments and our responses follow.

Comment: One commenter requested that we permit a physician to receive a productivity bonus based on services that the physician or the physician's ''care team'' has personally performed, provided that the productivity bonus is not determined in any manner that is directly related to the volume or value of the physician's referrals of designated health services.

Response: Whether or not a productivity bonus paid to a physician in a group practice would violate the prohibition on compensation that takes into account the volume or value of the physician's referrals at § 411.352(g) depends on the basis for the productivity bonus. To the extent that a productivity bonus (or the portion of a productivity bonus) paid by a group practice to a physician in the group is solely based on services personally performed by the physician (which are not referrals, even if they are designated health services), the productivity bonus (or the portion of the productivity bonus) would not violate § 411.352(g). To the extent that a productivity bonus (or the portion of a productivity bonus) paid by a group practice to a physician in the group is solely based on services performed by a member of the physician's care team that are not designated health services, the productivity bonus (or the portion of the productivity bonus) would not violate § 411.352(g). To the extent that a productivity bonus (or the portion of a productivity bonus) paid by a group practice to a physician in the group is solely based on designated health services ordered by the physician and furnished by members of the physician's care team ''incident to'' the physician's services and billed to Medicare as such, the productivity bonus (or the portion of the productivity bonus) would not violate § 411.352(g). To the extent that a productivity bonus (or the portion of a productivity bonus) paid by a group practice to a physician in the group is solely based on designated health services ordered by the physician and furnished by members of the physician's care team, but not furnished ''incident to'' the physician's services, the productivity bonus (or the portion of the productivity bonus) may only indirectly relate to the volume or value of the physician's referrals for the designated health services furnished by the members of the physician's care team.

Comment: Most commenters that commented on our solicitation regarding whether the deeming provision related to the relative value units personally performed by a physician did not support a limitation of this deeming methodology to only the physician's relative value units as defined at § 414.22. Commenters urged us to finalize our proposal to include as a deemed permissible productivity bonus methodology one that is based on the physician's total patient encounters. One commenter urged us not to make any revision to this regulation, stating that it works as currently structured and revising it would create additional regulatory burden.

Response: We are finalizing § 411.352(i)(2)(ii)(A) as proposed. Under our longstanding regulations, as well as those proposed, a physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed or services ''incident to'' such

personally performed services (or both). The productivity bonus may not be determined in any manner that is directly related to the volume or value of referrals by the physician, except that the productivity bonus may directly relate to the volume or value of referrals by the physician if the referrals are for services ''incident to'' the physician's personally performed services. The regulation at § 414.22(a) relates to the establishment of physician work RVUs. The regulation at § 414.22(b) relates to the computation of practice expense RVUs. The regulation at § 414.22(c) relates to the computation of malpractice expense RVUs. We believe the reference to § 414.22 generally to describe a ''physician's RVUs'' is misplaced in our current regulations. Our clarification is intended only to marry the general requirement for productivity bonuses based on services that are personally performed by a physician with the deeming provision that allows productivity bonuses based on total patient encounters or RVUs. It is not intended to, nor do we believe it will, limit the payment of productivity bonuses currently permissible under our regulations. Therefore, we see no reason why the revisions finalized at § 411.352(i)(2)(ii)(A) would create additional regulatory burden for group practices.

D. Recalibrating the Scope and Application of the Regulations

As we stated previously and in our Phase I rulemaking, our intent in implementing section 1877 of the Act was ''to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory language and intent'' (66 FR 860). One purpose of this final rule is to reexamine our current regulations to assess whether we have held true to that intention. In doing so, we have considered our own experience in administering the SRDP, stakeholder interactions, comments to the CMS RFI and to our proposed rule, and our experience working with our law enforcement partners. In the proposed rule, we proposed revisions to, including deletions of, certain requirements in our regulatory exceptions. In this section II.D. of the final rule, we explain which of our proposals to recalibrate the scope and application of the physician self-referral regulations that we are finalizing and any modifications resulting from our consideration of the comments on the proposed rule.

1. Decoupling the Physician Self-Referral Law From the Federal Anti-Kickback Statute and Federal and State Laws or Regulations Governing Billing or Claims Submission

Section 1877 of the Act established numerous exceptions to the statute's referral and billing prohibitions and granted the Secretary authority to establish regulatory exceptions for other financial relationships that do not pose a risk of program or patient abuse. The majority of the exceptions issued using the Secretary's authority under section 1877(b)(4) of the Act (which we often refer to as the ''regulatory exceptions'') require that the arrangement does not violate the anti-kickback statute. Most of these exceptions also require that the arrangement does not violate any Federal or State law or regulation governing billing or claims submission.

In Phase I, we stated that the requirements pertaining to the anti-kickback statute and billing or claims submission are necessary in regulatory exceptions to ensure that the excepted financial relationships do not pose a risk of program or patient abuse (66 FR 863). Even though we acknowledged that the physician self-referral law and the anti-kickback statute are different statutes, we were concerned that, if the regulatory exceptions did not require compliance with the anti-kickback statute, unscrupulous physicians and entities could potentially protect intentional unlawful and abusive conduct by complying with the minimal requirements of a regulatory exception. In Phase II, we stated our interpretation that the statutory ''no risk'' standard is not limited to risks as determined under the physician self-referral law (69 FR 16108). We added that many arrangements that might otherwise warrant an exception under section 1877 of the Act—a strict liability statute—pose some degree of risk under the anti-kickback statute; these arrangements cannot, therefore, be said to pose *no* risk. Similarly, we stated that some arrangements that may be permissible under the physician self-referral law could pose a risk of violating certain laws pertaining to billing or claims submission. Therefore, we concluded that the regulatory exceptions created using the Secretary's authority under section 1877(b)(4) of the Act must require that the excepted financial relationship not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

A substantial number of CMS RFI commenters expressed opposition to the continued coupling of the physician self-referral law with the anti-kickback statute and other billing and claims submission laws, explaining the significant burden associated with the inclusion of these requirements in regulatory exceptions to the physician self-referral law. CMS RFI commenters noted that the physician self-referral law is a strict liability statute and compliance with each element of an exception is mandatory if the entity wishes to submit a claim for designated health services referred by a physician with which it has a financial relationship, while the anti-kickback statute is an intent-based criminal statute and compliance with a safe harbor is not required. These commenters asserted that the inclusion of a requirement for compliance with the anti-kickback statute is misplaced in an exception to the physician self-referral law because it introduces an intent-based requirement into a strict liability statute. The commenters further noted that this requirement can make it unreasonably difficult for entities to meet their burden of proof under § 411.353(c)(2) that a referral and claim for designated health services does not violate the physician self-referral law. CMS RFI commenters also noted that the requirement for compliance with the anti-kickback statute and the requirement pertaining to Federal or State laws or regulations governing billing or claims submission are not necessary, because parties remain subject to these laws or regulations, regardless of whether their financial relationships otherwise comply with the physician self-referral law. As discussed below, commenters on the proposed rule have many of these same concerns.

As we stated in the proposed rule, based on our experience working with our law enforcement partners in reviewing conduct that implicates the physician self-referral law and other Federal fraud and abuse laws, when a compensation arrangement violates the intent-based criminal anti-kickback statute, it will likely also fail to meet one or more of the key requirements of an exception to the physician self-referral law (84 FR 55803). That is, the compensation in such cases likely is not fair market value or is determined in a manner that takes into account the volume or value of the physician's referrals or other business generated for the entity. As noted in the proposed rule, since the Phase I regulation was issued, we are unaware of any instances of noncompliance with the physician self-referral law that turned solely on an underlying violation of the anti-kickback statute (or any other Federal or

State law governing billing or claims submission). We also emphasized in the proposed rule and reiterate here that, although we were considering removing the requirement that the arrangement does not violate the anti-kickback statute from some or all of the regulatory exceptions, we believe that the Secretary has the authority under the statute to impose a requirement that the financial relationship not violate the anti-kickback statute or any other requirement if the Secretary determines it necessary and appropriate to ensure that an excepted financial relationship does not pose a risk of program or patient abuse. We also stated that we intend to monitor excepted financial relationships, and that we may propose in a future rulemaking to reinstate the requirements for deletion in some or all of the exceptions issued pursuant to the Secretary's statutory authority if we determine such requirements are necessary or appropriate to protect against program or patient abuse (84 FR 55802 through 55803).

Based on our experience working with our law enforcement partners since our regulations were finalized, as well as comments received in response to the CMS RFI, we stated in the proposed rule that we no longer believe that it is necessary or appropriate to include requirements pertaining to compliance with the anti-kickback statute and Federal and State laws or regulations governing billing or claims submission as requirements of the exceptions to the physician self-referral law. We noted further that the Congress did not require compliance with the anti-kickback statute or any other law in existence at the time of enactment of the statute or its subsequent revision in order to avoid the law's referral and billing prohibitions. Therefore, we proposed to remove from the exceptions in 42 CFR part 411, subpart J the requirement that the arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission wherever such requirements appear. Specifically, we proposed to remove the following sections from our regulations: § 411.353(f)(1)(iii); § 411.355(b)(4)(v), (e)(1)(iv), (f)(3), (f)(4), (g)(2), (g)(3), (h)(2), (h)(3), (i)(2), (i)(3), (j)(1)(iv); § 411.357(e)(4)(vii), (j)(3), (k)(1)(iii), (l)(5), (m)(7), (p)(3), (r)(2)(x), (s)(5), (t)(3)(iv), (u)(3), (w)(12), (x)(1)(viii), and (y)(8). We also proposed to delete the following clause from § 411.357(e)(6)(i) and (n): '', provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.'' Finally, we proposed to remove the definition of ''does not violate the anti-kickback statute'' in § 411.351. We noted that the exceptions for referral services at § 411.357(q) and obstetrical malpractice subsidies at § 411.357(r)(1) provide that arrangements satisfy the requirements of the exception if the arrangements comply with the requirements of certain specified safe harbors to the anti-kickback statute, and stated that our proposal did not apply to or affect these provisions.

After reviewing comments on our proposed rule, we no longer believe that it is appropriate to remove the requirement that the arrangement does not violate the anti-kickback statute from the exception for fair market value compensation at § 411.357(l), and we are not finalizing our proposal to remove that requirement at § 411.357(l)(5). We are finalizing our proposal to remove the requirement that the arrangement does not violate the anti-kickback statute from all other regulatory exceptions, and to remove requirements pertaining to Federal or State laws or regulations governing billing or claims submissions from all the regulatory exceptions, including § 411.357(l)(5). In the proposed rule, we noted that the Congress did not require compliance with the anti-kickback statute or any other law in existence at the time of enactment of the statute or its subsequent revision in order to avoid the physician self-referral law's referral and billing prohibitions (84 FR 55803). However, the regulatory exception for fair market value compensation at § 411.357(l) applies to many arrangements that also could be protected by a statutory exception. In particular, as explained in section II.D.10 of this final rule, we are finalizing our proposal to permit arrangements for the lease of office space to be excepted under § 411.357(l). The statutory exception for the rental of office space at section 1877(e)(1) of the Act and § 411.357(a) of our regulations requires, among other things, that the space rented or leased does not exceed that which is reasonable or necessary for the legitimate purposes of the lease and is used exclusively by the lessee when being used by the lessee. There are similar requirements in the statutory exception for the rental of equipment at § 411.357(b)(2). The regulatory exception for fair market value compensation, on the other hand, does not include such requirements. To the extent that the exception for fair market value compensation does not contain substitute requirements or safeguards, there is a possibility that certain potentially abusive arrangements that would not be permitted under a statutory exception could be protected by this regulatory exception.

We believe that requiring that the arrangement does not violate the anti-kickback statute in the exception for fair market value compensation at § 411.357(l) serves as a substitute safeguard, in lieu of certain safeguards that are included in the statutory exceptions but omitted from § 411.357(l). The exclusive use requirement in the statutory exceptions for the rental of office space and equipment, for example, prevents sham or ''paper'' leases, where a lessor receives payment from a lessee for space that the lessor continues to use (63 FR 1714 and 69 FR 16086). We believe that sham or paper lease arrangements would likely violate the anti-kickback statute. Therefore, the requirement at § 411.357(l)(5) that the arrangement not violate the anti-kickback statute provides a substitute safeguard for the statutory exclusive use requirement and serves to prevent program or patient abuse. Without the requirement that the arrangement not violate the anti-kickback statute, sham lease arrangements or other abusive arrangements could potentially be excepted under § 411.357(l), and the exception for fair market value compensation would not satisfy the requirement at section 1877(b)(4) of the Act that financial relationships protected by the exception do not pose a risk of program or patient abuse. On the other hand, we are no longer convinced that the requirement at § 411.357(l)(5) that an arrangement must not violate Federal or State laws or regulations governing billing or claims submission is needed as a substitute safeguard to prevent program or patient abuse, and we are therefore finalizing the proposal to remove that requirement from § 411.357(l)(5). In sum, the exception for fair market value compensation offers greater flexibility than certain overlapping statutory exceptions insofar as it omits some statutory requirements, but the greater flexibility could, in certain instances, increase the risk of program or patient abuse. Therefore, the requirement that the arrangement does not violate the anti-kickback statute should not be deleted from § 411.357(l)(5).

We emphasized in the proposed rule and reiterate here that our final rule in no way affects parties' liability under the anti-kickback statute. Indeed, the Congress clarified when enacting section 1877 of the Act that ''any

prohibition, exemption, or exception authorized under this provision in no way alters (or reflects on) the scope and application of the anti-kickback provisions in section 1128B of the Social Security Act'' (H. Report 101–386, 856 (1989)). Most importantly, the fact that a financial relationship satisfies the requirements of an applicable exception to the physician self-referral law does *not* entail that the financial relationship does not violate the anti-kickback statute. (*See* 66 FR 879.) Similarly, compliance with the anti-kickback statute does not entail compliance with the physician self-referral law. To the extent that a financial relationship is governed by other laws or regulations, our action does not affect the parties' compliance obligations under those other laws or regulations. Specifically, claims submitted to the Medicare program must comply with all laws, regulations, and other requirements governing billing and claims submission.

After reviewing the comments on the proposed rule, we are finalizing our proposal to remove the requirement that an arrangement not violate the anti-kickback statute from all the regulatory exceptions except the exception for fair market value compensation at § 411.357(l). Because this requirement will remain in § 411.357(l), we are not finalizing our proposal to delete the definition of ''does not violate the anti-kickback statute'' at § 411.351. We are finalizing without modification our proposal to remove from all the applicable regulatory exceptions the requirement that an arrangement not violate any Federal or State law or regulation governing billing and claims submissions.

We received the following comments and our responses follow.

Comment: Nearly all the commenters that addressed the proposal favored removing provisions requiring that the arrangement does not violate the anti-kickback statute or Federal and State laws or regulations governing billing and claims submissions from the regulatory exceptions. The commenters stated that the requirements are unnecessary because parties must comply with these laws independently of the physician self-referral law. One of these commenters stated that removing the requirement that an arrangement that satisfies an exception to the physician self-referral law must also fit within a safe harbor under the anti-kickback is a welcome streamlining of the regulations. Some commenters stressed that the incorporation of the intent-based Federal anti-kickback statute into the strict-liability framework of the physician self-referral law causes confusion and compliance risk without affording any additional protection of the Medicare program. Commenters in favor of removing the requirement that the arrangement does not violate the anti-kickback statute also requested that CMS delete the definition of ''does not violate the anti-kickback statute'' in § 411.351. One of these commenters maintained that the definition is circular, because it includes the phrase ''does not violate the anti-kickback provision in section 1128B(b) of the Act.'' Lastly, one commenter generally opposed removing the requirement that the arrangement does not violate the anti-kickback statute from the regulatory exceptions, stating that finalizing the proposal would lead to program or patient abuse.

Response: We agree with the majority of the commenters that the requirement that an arrangement not violate any Federal or State law or regulation governing billing or claims submission should be removed from all the regulatory exceptions. Parties have an independent obligation to follow such laws, and we no longer believe that the Secretary must require compliance with such laws and regulations to ensure that financial relationships excepted under a regulatory exception do not pose a risk of program or patient abuse.

With respect to the anti-kickback statute, we continue to believe that, as a general matter, the requirement that the arrangement does not violate the anti-kickback statute in most regulatory exceptions would not further protect against program or patient abuse because the parties to the compensation arrangement are already required to comply with all Federal laws, including the anti-kickback statute. We understand the concerns raised by commenters that inclusion of the intent-based anti-kickback statute in the strict liability framework of the physician self-referral law may increase the burden of compliance with the physician self-referral law, and we are finalizing our proposal to remove this requirement from all regulatory exceptions except the exception at § 411.357(l) for fair market value compensation. As previously noted in this final rule, the requirement that the arrangement does not violate the anti-kickback statute in § 411.357(l)(5) is an important substitute requirement for certain statutory requirements that would otherwise apply to arrangements to which the regulatory exception at § 411.357(l) is applicable, such as the exclusive use requirement for leases of office space and equipment. Given the current requirements in the exception for fair market value compensation, we are not convinced that it is appropriate to protect leases of office space and certain other arrangements under § 411.357(l) without the requirement that the arrangement does not violate the anti-kickback statute. Thus, we are not finalizing our proposal to remove this requirement from § 411.357(l)(5).

Because we are not finalizing our proposal to remove the requirement that the arrangement does not violate the anti-kickback statute from the exception for fair market value compensation, we are not deleting the definition of ''does not violate the anti-kickback statute'' at § 411.351. We note that the requirement that the arrangement does not violate the anti-kickback statute at § 411.357(l)(5) does not and never has required that an arrangement fit into a safe harbor under the anti-kickback statute; rather the requirement remains that the arrangement does not violate the anti-kickback statute. As the term is defined at § 411.351, an arrangement ''does not violate the anti-kickback statute'' if it meets a safe harbor under the anti-kickback statute, has been specifically approved by OIG in a favorable advisory opinion issued to a party to the particular arrangement with respect to the particular arrangement (and not a similar arrangement), or does not violate the anti-kickback provisions in section 1128B(b) of the Act. We did not propose and are not finalizing any specific substantive modifications of this definition.

Lastly, we are taking this opportunity to reiterate that the Secretary retains the authority to impose, in future rulemaking, requirements pertaining to the anti-kickback statute and Federal or State laws or regulations governing billing or claims submissions in some or all of the regulatory exceptions issued under section 1877(b)(4) of the Act, if the Secretary determines that such requirements are necessary to prevent program or patient abuse. We intend to monitor excepted financial relationships, and we may propose in a future rulemaking to include the requirements in some or all of the exceptions issued pursuant to the Secretary's authority if we determine such requirements are necessary or appropriate to protect against program or patient abuse.

2. Definitions (§ 411.351)

a. Designated Health Services

Section 1877(1)(A) of the Act provides that, unless the requirements of an applicable exception are satisfied, if a physician (or an immediate family member of a physician) has a financial

relationship with an entity, the physician may not make a referral to the entity for the furnishing of a designated health service for which payment may otherwise be made under Title XVIII of the Act (that is, Medicare). The referral prohibition is codified in our regulations at § 411.353(a). In the 1998 proposed rule, we interpreted the phrase ''designated health service for which payment otherwise may be made'' broadly to mean ''any designated health service that ordinarily 'may be' covered under Medicare (that is, that could be a covered service under Medicare in the community in which the service has been provided) for a Medicare-eligible individual, regardless of whether Medicare would actually pay for this particular service, at the time, for that particular individual (for example, the individual may not have met his or her deductible)'' (63 FR 1694). Our definition of the term ''designated health services'' in the 1998 proposed rule was consistent with this broad interpretation of the referral prohibition.

Section 1877(h)(6) of the Act defines ''designated health services'' by listing various categories of services that qualify as designated health services (for example, clinical laboratory services). In the 1998 proposed rule, we stated that a designated health service remains such ''even if it is billed as something else or is subsumed within another service category by being bundled with other services for billing purposes'' (63 FR 1673). By way of example, we stated that clinical laboratory services that are provided by a skilled nursing facility (SNF) and reimbursed as part of the SNF composite rate would remain designated health services for purposes of section 1877 of the Act, even though SNF services are not listed as designated health services at section 1877(h)(6) of the Act and Medicare would not separately pay for the clinical laboratory service furnished by the SNF. The now-deleted exception at § 411.355(d), which was first finalized in the 1995 final rule, served as a counterbalance to the broad interpretation of designated health services that was proposed in the 1998 proposed rule. As finalized in the 1995 final rule, § 411.355(d) provided that the referral prohibition in § 411.353 did not apply to services furnished in an ambulatory surgical center (ASC) or end-stage renal disease (ESRD) facility, or by a hospice, if payment for those services was included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge (60 FR 41980). We explained that the application of a composite rate payment ''constitutes a barrier to either Medicare program or patient abuse because the Medicare program will pay only a set amount to the facilities irrespective of the number and frequency of laboratory tests that are ordered'' (60 FR 41940). In the 1998 proposed rule, we proposed an amendment to § 411.355(d) that would have excepted services furnished under other payment rates that that the Secretary determines provide no financial incentive for under- or overutilization or any other risk of program or patient abuse (63 FR 1666). However, in Phase I, instead of expanding the exception at § 411.355(d) to include services furnished under other payment rates, we narrowed the definition of ''designated health services'' to exclude certain services that are paid as part of a composite rate, and solicited comments on whether the exception at § 411.355(d) was still necessary in light of the narrowed definition of ''designated health services'' (66 FR 923 through 924). We ultimately determined in Phase II that § 411.355(d) was no longer necessary, given the change to the definition of ''designated health services'' finalized in Phase I, and we removed the exception from our regulations (69 FR 16111).

As finalized in Phase I, the definition of ''designated health services'' includes only designated health services payable, in whole or in part, by Medicare, and does not include services that would otherwise constitute designated health services, but that are reimbursed by Medicare as part of a composite rate, except to the extent that the services are specifically identified in § 411.351 and are themselves payable through a composite rate. SNF services paid by Medicare under the Part A composite rate (that is, the Skilled Nursing Facility Prospective Payment System (SNF PPS)), for example, are not designated health services, even if the bundle of services includes services that would otherwise be designated health services, such as clinical laboratory services.[9] In contrast, although home health and inpatient and outpatient hospital services are paid under a composite rate, they remain designated health services under the definition finalized in Phase I because section 1877(h)(6) of the Act explicitly lists these services as designated health services. We explained in Phase I that our ultimate definition of ''designated health services'' was based on issues of statutory construction (66 FR 923). In particular, commenters on the 1998 proposed rule asserted that the definition of designated health services would have expanded the list of services that are considered to be designated health services beyond the services explicitly listed at section 1877(h)(1) of the Act. For example, clinical laboratory services furnished by a SNF and reimbursed under the SNF PPS would have been considered designated health services under the definition, even though SNF services are not included in the statutory list of designated health services. The commenters maintained that, where the Congress intended the physician self-referral law to cover specific services, including services that are paid under a composite rate such as home health services, it did so by explicitly listing the services at section 1877(h)(6) of the Act. We agreed and finalized the definition of ''designated health services'' to include only those services paid under a composite rate that are explicitly listed at section 1877(h)(1) of the Act; that is, home health services and inpatient and outpatient hospital services.

As we stated in the proposed rule, in light of our experience with the SRDP and our review of the comments to the CMS RFI, we reviewed the regulatory history of our definition of ''designated health services'' at § 411.351 to identify whether further clarification regarding what constitutes a designated health service is necessary (84 FR 55805). We proposed to revise the definition of ''designated health services'' to clarify that a service provided by a hospital to an inpatient does not constitute a designated health service payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS). To illustrate, suppose that, after an inpatient has been admitted to a hospital under an established Medicare Severity Diagnosis Related Group (MS–DRG), the patient's attending physician requests a consultation with a specialist who was not responsible for the patient's admission, and the specialist orders an X-ray. By the time the specialist orders the X-ray, the rate of Medicare payment under the IPPS has already been established by the MS–DRG (diagnostic

[9] ESRD services are also reimbursed on a composite rate, and thus are not considered to be designated health services. In this context, we refer readers to the CY 2018 ERSD PPS Final Rule, where we explained that, for purposes of the physician self-referral law, the ''composite rate'' for ESRD services is interpreted as the per-treatment payment amount (82 FR 50751). To the extent that outpatient prescription drugs are included in the ESRD per-treatment payment amount, they do not qualify as designated health services.

imaging is bundled into the payment for the inpatient admission), and, unless the X-ray results in an outlier payment, the hospital will not receive any additional payment for the service over and above the payment rate established by the MS–DRG. Moreover, insofar as the provision of the X-ray does not affect the rate of payment, the physician has no financial incentive to over-prescribe the service. As illustrated here, we do not believe that the X-ray is a designated health service that is payable, in whole or part, by Medicare, and our definition of ''designated health services'' at § 411.351 would exclude this service from the definition of designated health services, even though it falls within a category of services that, when billed separately, would be ''designated health services.'' Thus, assuming the specialist had a financial relationship with the hospital that failed to satisfy the requirements of an applicable exception to the physician self-referral law at the time the X-ray was ordered, the inpatient hospital services would not be tainted by the unexcepted financial relationship, and the hospital would not be prohibited from billing Medicare for the admission. On the other hand, if the physician who ordered the inpatient hospital admission had a financial relationship with the hospital that failed to satisfy the requirements of an applicable exception, § 411.353(b) would prohibit the hospital for billing for the inpatient hospital services. In the proposed rule, we stated that we are aware that not all hospitals are paid under the IPPS (84 FR 55805). We solicited comments as to whether our proposal regarding certain hospital services that are not ''designated health services payable, in whole or in part, by Medicare'' should be extended to analogous services provided by hospitals that are not paid under the IPPS, and, if so, how we should effectuate this change in our regulation text. We also stated that, although hospital outpatient services are also paid under a composite rate, we believe that there is typically only one ordering physician for outpatient services, and it would be rare for a physician other than the ordering physician to refer an outpatient for additional hospital outpatient services that are compensated within the same ambulatory payment classification (APC) under the Hospital Outpatient Prospective Payment System (OPPS). For this reason, we did not propose to apply the modified definition of ''designated health services'' at § 411.351 to outpatient hospital services paid under the OPPS.

In this final rule, we are extending the proposed policy to apply to hospital services furnished to inpatients that are paid under additional prospective payment systems. Specifically, we are revising the definition of ''designated health services'' to state that, for services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS): (i) Acute Care Hospital Inpatient (IPPS); (ii) Inpatient Rehabilitation Facility (IRF PPS); (iii) Inpatient Psychiatric Facility (IPF PPS); or (iv) Long-Term Care Hospital (LTCH PPS). For the reasons explained in our response to comments below, we are not extending the proposed policy to apply to hospital services furnished to outpatients. We are also making nonsubstantive revisions to the definition of ''designated health services'' for consistency regarding the terms ''paid'' and ''payable'' and making a minor grammatical change.

We received the following comments and our responses follow.

Comment: The vast majority of commenters that commented on this proposal supported our proposal to exclude from the definition of ''designated health service payable, in whole or in part, by Medicare'' those services furnished by a hospital to an inpatient that do not affect the amount of Medicare's payment to the hospital under the IPPS. Commenters indicated that the revision would bring clarity to hospitals when assessing compliance with the physician self-referral law and calculating potential overpayments for violations of the law. Some commenters highlighted the onerous compliance burdens associated with quantifying a potential overpayment when the financial relationship that does not satisfy the requirements of an applicable exception is with a physician other than the physician who referred the patient for the inpatient admission. Nearly all of the commenters that supported our proposal requested that we expand the policy to other composite rate payment systems under which hospitals are paid. Some commenters suggested limiting the expansion to payments for services to inpatients under the IRF PPS, IPF PPS, and LTCH PPS. Other commenters suggested that we expand the policy to any composite rate payment system under which a hospital is paid for either inpatient or outpatient services, including OPPS. The commenters suggesting expansion to OPPS stated (in identical language) that they are aware of circumstances where physicians other than the ordering physician refer outpatients for additional outpatient services that would not be compensated separately under the OPPS; however, none of these commenters provided a specific example or identified a specific APC.

Response: We believe that expanding our policy to other payment systems applicable to the furnishing of services to inpatients would not pose a risk of program or patient abuse. The IRF PPS, IPF PPS, and LTCH PPS operate similarly to IPPS. No additional payment is available where additional hospital services are ordered after a patient's admission by a physician who was not responsible for the patient's admission, except in limited circumstances. We are not persuaded to expand the policy to the OPPS. As we stated in the proposed rule, we believe that there is typically only one ordering physician for outpatient services, and it would be rare that a physician other than the ordering physician would refer an outpatient for additional outpatient services that would not be paid separately under the OPPS (84 FR 55805). The commenters that asserted the existence of circumstances where physicians other than the ordering physician refer outpatients for additional outpatient services that would not be paid separately under the OPPS provided no evidence or examples of such circumstances for us to confirm. Finally, we believe that extending the rule to designated health services paid under the OPPS would be burdensome and challenging for stakeholders, CMS, and our law enforcement partners to implement and enforce. We decline to extend the policy to the OPPS.

Comment: One commenter questioned whether a service would be considered a designated health service if the hospital's furnishing of the service to an inpatient decreased the IPPS payment to the hospital. Another commenter requested clarification of the meaning of ''affects'' the amount of Medicare payment. A few commenters requested additional examples of hospital services that would or would not ''affect'' an IPPS payment under the revised definition of ''designated health services,'' if finalized.

Response: Although we do not believe it is likely that the ordering of additional services for an inpatient would decrease the amount of Medicare's payment for the admission, we are replacing the word ''affect'' with ''increase'' to express our policy with more precision. As noted, under the definition of ''designated health

services'' finalized at § 411.351, for services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS): (i) Acute Care Hospital Inpatient (IPPS); (ii) Inpatient Rehabilitation Facility (IRF PPS); (iii) Inpatient Psychiatric Facility (IPF PPS); or (iv) Long-Term Care Hospital (LTCH PPS).

Comment: One commenter in opposition to our proposal described a summary of the proposed rule prepared by an independent law firm that identified what the law firm assumed the rationale behind our proposal to be: Physicians have no financial incentive to overprescribe services that do not affect the rate of payment. The commenter disagreed with that rationale as support for our proposal, and described a complicated situation that could present a risk of abuse based on *hospital* referrals to service lines within the hospital in which certain physicians, but not the referring physicians addressed in our proposal, could profit. The commenter expressed concern that the revised definition of ''designated health services'' would likely eliminate inpatient hospitalization from the reach of the physician self-referral law. The commenter also asserted that there exists no opposition to the current definition of ''designated health services'' and urged CMS not to finalize the proposal.

Response: All inpatient and outpatient hospital services will remain designated health services except for services furnished to an inpatient after he or she becomes an inpatient and only where those additional services do not increase the amount of Medicare's payment to the hospital for the inpatient admission. For the reasons stated in the proposed rule and in this final rule, we are finalizing our proposal with the modification described above.

Comment: A few commenters expressed uncertainty with respect to a hospital's ability to know *whether* services furnished to an inpatient pursuant to a prohibited referral from a physician other than the physician who made the referral for the inpatient admission result in outlier payments under the IPPS such that the ''caveat'' in the exclusion from the definition would apply. The commenters also stated that they lacked clarity regarding *when* a hospital could know that an outlier payment is triggered by a particular inpatient admission. The commenters asserted that this makes the revised definition of ''designated health services'' unworkable.

Response: We see no reason why a hospital would be unable to identify referrals made by physicians with whom the hospital has financial relationships that do not satisfy the requirements of an applicable exception. As we have stated repeatedly throughout our rulemaking history, the physician self-referral law's billing prohibition requires that the entity submitting a claim to Medicare for payment for designated health services has the burden of ensuring that the services were not furnished as a result of a prohibited referral. It is incumbent upon hospitals to implement effective compliance programs to identify financial relationships with physicians that do not satisfy the requirements of an applicable exception to the physician self-referral law and take action not to submit prohibited claims for payment. If a hospital did not identify the financial relationship with a referring physician until after a claim was submitted and paid, the hospital would need to identify admissions for which payments in excess of the expected MS–DRG payment (or other PPS payment) were received and identify any prohibited referrals for services furnished to the inpatients for whom the excess payments relate. We believe that our rules and regulations regarding outlier payments are clear and we are unaware of any reason that a hospital would be unable to utilize its medical record and billing systems to identify inpatient admissions that resulted in payments in addition to the expected MS–DRG payment (or other PPS payment) for the inpatient admission.

b. Physician

In the 1992 proposed rule, we stated that, for purposes of the physician self-referral law, physicians are certain professionals who are ''legally authorized to practice by the State in which they perform their professional functions or actions and when they are acting within the scope of their licenses.'' (57 FR 8593). We included in the definition a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of optometry, and a chiropractor who meets certain qualifications. In Phase I, we finalized our definition of ''physician'' at § 411.351, defining the term as ''a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined at section 1861(r) of the Act.'' (66 FR 955). Since Phase I, our definition of ''physician'' at § 411.351 has consistently referred to the definition of ''physician'' at section 1861(r) of the Act. However, although the definition of ''physician'' at § 411.351 cross-references section 1861(r) of the Act, the two definitions are not entirely harmonious. In particular, the definition of ''physician'' at § 411.351 does not include all the limitations imposed by the definition of ''physician'' at section 1861(r) of the Act. In order to correct this discrepancy and provide uniformity between Title XVIII of the Act and our regulations with regard to the definition of a ''physician,'' in the proposed rule, we proposed to amend the definition of ''physician'' at § 411.351 (84 FR 55805 through 55806). Under the proposed definition, the types of practitioners who qualify as ''physicians'' for purposes of the physician self-referral law would be defined by cross-reference to section 1861(r) of the Act. Therefore, the definition of ''physician'' at § 411.351 would incorporate the statutory limitations imposed on the definition of ''physician'' by section 1861(r) of the Act. As proposed, the definition at § 411.351 would continue to provide that a physician is considered the same as his or her professional corporation for purposes of the physician self-referral law. After reviewing the comments, we are finalizing the definition of ''physician'' as proposed.

We received the following comment and our response follows.

Comment: Several commenters generally supported the regulatory change to cross-reference the definition of ''physician'' at § 411.351 to the definition in section 1861 of the Act. A few commenters maintained that the definition of ''physician'' should be limited to doctors who have a Doctor of Medicine, Doctor of Osteopathic Medicine, or a recognized equivalent physician degree. One commenter questioned the practical effect of incorporating into our definition of physician at § 411.351 the statutory limitations imposed in the definition of ''physician'' under section 1861(r) of the Act. Specifically, the commenter asked whether the policy excludes podiatrists, optometrists, and chiropractors from the definition of ''physician'' for purposes of the physician self-referral law, because, according to the commenter, the statutory limitations related to those three types of practitioners restrict when they are considered physicians under section 1861(r) of the Act to very limited circumstances, none of which reference the physician self-referral law.

Response: We are finalizing the definition of ''physician'' as proposed.

The revised definition will align the regulatory definition of ''physician'' at § 411.351 with the statutory definition of ''physician'' in section 1861(r) of the Act to ensure that there are no inconsistencies between our regulations and the statutory definition. Because the physician self-referral statute is in Title XVIII of the Act, in the absence of a definition of ''physician'' in section 1877 of the Act, definitions of general applicability, such as the definition of ''physician'' at section 1861(r) of the Act, are applicable to the physician self-referral law. Under section 1861(r) of the Act, a ''physician'' includes a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor, but provides for limitations on when such doctors are considered ''physicians'' for purposes of Title XVIII of the Act. We do not believe that the definition of ''physician'' in our regulations should be either more limited or more expansive than the statutory definition. Thus, to the extent that the statutory definition of ''physician'' includes doctors other than doctors of medicine and osteopathy, those practitioners fall within the ambit of the physician self-referral law. However, we do not believe that the referral prohibition at § 411.353(a) should apply to any doctor during the period he or she is not considered to be a physician for purposes of Title XVIII of the Act. In those instances when a doctor of medicine or osteopathy, doctor of dental surgery or dental medicine, doctor of podiatric medicine, doctor of optometry, or chiropractor is considered a physician under section 1861(r) of the Act, the doctor or chiropractor will be considered a physician for purposes of the physician self-referral law.

c. Referral

In Phase II, we stated that the exception for fair market value compensation is not available to protect recruitment arrangements (69 FR 16096). We noted that a hospital is not permitted to pay a physician for the benefit of receiving the physician's referrals, and that such payments are antithetical to the premise of the statute. In the proposed rule, we reaffirmed that a physician's referrals are not items or services for which payment may be made under the physician self-referral law, and that neither the existing exceptions to the physician self-referral law nor the exceptions proposed in the proposed rule would protect such payments. We proposed to revise the definition of ''referral'' at § 411.351 to explicitly state our longstanding policy that a referral is not an item or service for purposes of section 1877 of the Act and the physician self-referral regulations (84 FR 55806). After reviewing the comments, we are finalizing our modification of the definition of ''referral'' as proposed.

We received the following comment and our response follows.

Comment: Numerous commenters supported the proposed revision of the definition of ''referral.'' We also received comments on our proposed definition of ''referral'' that pertained to the volume or value standard and the payment of productivity bonuses.

Response: We are finalizing the definition as proposed. Comments pertaining to the volume or value standard and the payment of productivity bonuses are addressed in section II.B.3. of this final rule.

d. Remuneration

A compensation arrangement between a physician (or an immediate family member of such physician) and an entity (as defined at § 411.351) implicates the referral and billing prohibitions of the physician self-referral law. Section 1877(h)(1)(A) of the Act defines the term ''compensation arrangement'' as any arrangement involving any ''remuneration'' between a physician (or an immediate family member of such physician) and an entity. However, section 1877(h)(1)(C) of the Act identifies certain types of remuneration which, if provided, would not create a compensation arrangement subject to the referral and billing prohibitions of the physician self-referral law. Under section 1877(h)(1)(C)(ii) of the Act, the provision of the following does not create a compensation arrangement between the parties: Items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies, or to order or communicate the results of tests or procedures for such entity. Furthermore, under our definition of ''remuneration'' at § 411.351, the provision of such items, devices, or supplies is not considered to be remuneration.

In the 1998 proposed rule we explained our interpretation of the phrase ''used solely'' at section 1877(h)(1)(C)(ii) of the Act (66 FR 1693 through 1694). We observed that some pathology laboratories had been furnishing physicians with materials ranging from basic collection and storage items to more specialized or sophisticated items, devices, or equipment. We clarified that, in order for these items and devices to meet the statutory requirement, they must be used *solely* to collect, transport, process, or store specimens for the entity that provided the items and devices, or to order or communicate the results of tests or procedures for such entity. We provided examples of items that could meet the ''used solely'' test, including cups used for urine collection or vials used to hold and transport blood to the entity that supplied the items or devices. We emphasized that an item or device would not meet the ''used solely'' requirement if it is used for any purpose besides the purposes listed in the statute. In particular, we noted that certain surgical tools that can be used to collect or store samples, but are also routinely used as part of a surgical or medical procedure, would not satisfy the ''used solely'' requirement.

As finalized in Phase I, the definition of ''remuneration'' included a parenthetical stipulating that the provision of surgical items, devices, and supplies would not qualify for the carve-out to the definition of ''remuneration'' for items, devices, or supplies that are used solely for the purposes listed at section 1877(h)(1)(C)(ii) of the Act (66 FR 947). We explained that we did not believe that the Congress intended section 1877(h)(1)(C)(ii) of the Act to allow entities to supply physicians with surgical items for free or below fair market value prices, noting that such items may have independent economic value to physicians apart from the six statutorily permitted uses. We stated our belief that the Congress intended to include at section 1877(h)(1)(C)(ii) of the Act single-use items, devices, and supplies of low value that are primarily provided by laboratories to ensure proper collection of specimens. In this context, we explained that reusable items may have value to physicians unrelated to the collection of specimens, and therefore could not meet the ''used solely'' requirement. Lastly, we stated that the provision of an excessive number of collection supplies creates an inference that the supplies are not provided ''solely'' to collect, transport, process, or store specimens for the entity that furnished them.

We made no changes to the definition of ''remuneration'' in Phase II or Phase III. In the CY 2016 PFS final rule, we clarified that the provision of an item, device, or supply that is used for *one or more* of the six purposes listed in the statute, and no other purpose, does not constitute remuneration (80 FR 71321). In two advisory opinions issued in 2013 we applied the definition of ''remuneration'' at § 411.351 to two proposed arrangements to provide

certain devices to physicians free of charge. In CMS–AO–2013–01, we concluded that, based on the specific facts certified by the requestor of the opinion, the provision of liquid-based Pap smear specimen collection kits did not constitute remuneration, because the collection kits are not surgical devices, and because the devices are used solely in the collection of specimens. Among other things, our ''used solely'' analysis highlighted the following facts, as certified by the requestor: (1) The Pap smear collection kits contain only disposable items that cannot be reused after a specimen is collected; and (2) the entity furnishing the Pap smear collection kits has a system in place to ensure that physicians receive only the quantity of devices necessary for their practice needs, and to address potential instances of separation of the devices into their component parts for use other than to collect specimens. In contrast, in CMS–AO–2013–02, we concluded that, based on the specific facts certified by the requestor of the opinion, the furnishing of certain disposable biopsy brushes for use in obtaining a biopsy of visible exocervical lesions constituted remuneration under the definition at § 411.351. We noted that, as certified by the requestor, the biopsy brush is a disposable, single-use, cervical biopsy device that is used to collect a specimen to be sent to a laboratory. After reviewing FDA rules and regulations and American Medical Association guidelines, and consulting with CMS medical officers, we concluded that the device is a ''surgical item, device, or supply'' for purposes of the physician self-referral law and, therefore, that the provision of the device constitutes remuneration under § 411.351.

After further consideration of our interpretation of section 1877(h)(1)(C)(ii) of the Act and the analysis set forth in the 2013 advisory opinions, in the proposed rule, we proposed certain modifications to the definition of ''remuneration'' at § 411.351 (84 FR 55806 through 55807). Specifically, we proposed to remove the parenthetical in the current definition of ''remuneration,'' which stipulates that the carve-out to the definition of ''remuneration'' does not apply to surgical items, devices, or supplies. We stated that we are no longer convinced that the mere fact that an item, device, or supply is routinely used as part of a surgical procedure means that the item, device, or supply is not used solely for one of the six purposes listed at section 1877(h)(1)(C)(ii) of the Act. Rather, the relevant inquiry for purposes of the physician self-referral law is whether the item, device, or supply is used solely for one or more of the statutory purposes, regardless of whether the device is also classified as a surgical device. To be clear, we continue to believe that the Congress intended the carve-out at section 1877(h)(1)(C)(ii) of the Act to cover single-use items, devices, or supplies of low value [10] that are primarily provided by laboratories to ensure proper collection of specimens, but we are no longer convinced that the mere fact that an item, supply, or device is classified as a ''surgical device'' means that it does not fall within the carve-out.

In the proposed rule, we also clarified the ''used solely'' requirement at § 411.351. Although the furnished item, device, or supply may not be used for any purpose other than one or more of the six purposes listed in the statute, we recognize that, in many instances, the item, device, or supply could theoretically be used for numerous purposes. For example, a specimen lockbox could potentially be used for several purposes; it could be used to store unused specimen collection supplies or as a doorstop. However, if, during the course of the arrangement, the specimen box provided to the physician is not used for any of these purposes and is, in fact, used only for one or more of the six purposes outlined in the statute and our regulations, the furnishing of the specimen box would not be considered remuneration between parties. In other words, the mere fact that an item, device, or supply *could* be used for a purpose other than one or more of the permitted purposes does not automatically mean that the furnishing of the item, device, or supply at no cost constitutes remuneration. We proposed to add the phrase ''in fact'' to the ''used solely'' requirement to clarify that an item, device, or supply can have several uses, including uses that are not among the six purposes listed in the statute; however, the furnishing of such items, supplies, or devices would not be considered remuneration if the item, device, or supply in question is, in fact, only used for one or more of the six purposes outlined in the statute. We again refer readers to the guidance provided in the 1998 proposed rule and in Phase I on steps that a party can take to ensure that the furnished items, supplies, or devices are used appropriately (63 FR 1693 through 1694 and 66 FR 947 through 948, respectively).

Although we proposed certain modifications to the definition of ''remuneration,'' we did not propose to exclude from the definition of ''remuneration'' those items, devices, or supplies whose main function is to prevent contamination or infection, even if the item, device, or supply could potentially be used for one or more of the six statutory purposes at section 1877(h)(1)(C)(ii) of the Act. In Phase I, we made clear that, although sterile gloves are essential to the proper collection of specimens, we believe they are not items, devices, or supplies that are used *solely* to collect, transport, process, or store specimens (66 FR 948). Sterile gloves are essential to the specimen collection process, but their primary purpose is to prevent infection or contamination. In addition, sterile gloves are fungible, general purpose items, and we continue to believe it would be impractical for parties to monitor the use of the gloves to ensure that they are used solely for one or more of the purposes listed at section 1877(h)(1)(C)(ii) of the Act. Likewise, although there may be certain specialized equipment (including surgical tools) that may be used for one or more of the purposes described in the statute, in order not to be considered remuneration, the item, device, or supply must not have a primary function of preventing infection or contamination, or some other purpose besides one of the six purposes listed in the statute.

After reviewing the comments, we are finalizing our revision of the definition of ''remuneration'' as proposed.

We received the following comments and our responses follow.

Comment: Numerous commenters supported our proposed revision of the definition of ''remuneration,'' including our proposal to remove the phrase ''not including surgical supplies, devices, or supplies'' and our proposal to clarify that items, devices, and supplies are not remuneration if they are, ''in fact,'' used exclusively for one or more of the permitted purposes. Several of the commenters that supported our proposed revision of the definition of ''remuneration'' also supported our statement that those items, devices, or supplies whose main function is to prevent contamination or infection are not carved out of the definition of ''remuneration.'' One commenter suggested that the proposed changes to the definition will reduce physician hesitancy regarding the acceptance of such items, devices, and supplies and will reduce administrative burden.

[10] *See,* for example, the OBRA 1993 Conference Report, H.R. 103–213 pp. 818 through 819, which characterized section 1877(h)(1)(C)(ii) of the Act as an ''exception'' for ''certain minor remuneration.''

Response: We agree that the revisions to the definition of ''remuneration'' will provide additional clarification and reduce administrative burden, and are revising the definition of ''remuneration'' as proposed.

Comment: One commenter objected to the proposal to strike the parenthetical pertaining to surgical items, devices, or supplies from the definition of ''remuneration'' and urged CMS not to finalize the proposal. The commenter maintained that CMS did not explain the rationale for the policy change in the proposed rule, and that CMS did not provide any examples of surgical items, devices, or supplies that would not be considered remuneration. According to the commenter, it is relatively straightforward for a laboratory to determine if an item, device, or supply is classified as ''surgical,'' and thus is not excluded from the definition of remuneration. The commenter asserted that it would be more difficult, if not impossible, for a laboratory to determine whether a physician in fact uses a surgical item, device, or supply for one of the permitted purposes under the statute. The commenter noted that CMS acknowledged in the proposed rule the difficulty of monitoring the use of sterile gloves. The commenter concluded that, given the difficulty of monitoring actual use, the proposal, if finalized, would create a ''slippery slope'' that would permit unscrupulous actors to provide items, devices, or supplies that are routinely used as part of a surgical procedure as opposed to one of the permitted purposes under the statute. A different commenter raised similar objections to the proposal. This commenter acknowledged that the proposal to no longer categorically include surgical items, devices, or supplies in the definition of ''remuneration'' provides some additional flexibility under our regulations, but urged CMS to ensure that the items, devices, or supplies not considered to be remuneration continue to be single-use items, devices, or supplies with little, if any, independent value to the physicians who receive them. The commenter expressed concern that, under the proposal, valuable items, devices, or supplies, such as bone marrow kits, would no longer be considered remuneration, thus increasing the risk of program or patient abuse. The commenter also expressed concern that it would increase the burden on parties to monitor the use of items, devices, or services, to ensure that physicians are in fact using the items, devices, or services for one or more of the permitted purposes under the statute.

Response: The purpose of the revision to the definition of ''remuneration'' is to increase flexibility under our regulations and to clarify the ''used solely'' requirement. As noted in the proposed rule, we no longer believe that the mere fact that an item, device, or supply is classified as ''surgical'' means that the item, device, or supply is not used solely for one or more of the permitted purposes. Although the categorical inclusion of surgical items, devices, or supplies in the definition of ''remuneration'' may provide a bright line test for determining which items may be furnished to physicians at reduced or no cost, it also may include certain items, device, or supplies in the definition of ''remuneration'' that the Congress meant to exclude in section 1877(h)(1)(C)(ii) of the Act. Nothing in the regulation compels an entity to provide any item, device, or supply to a physician below fair market value or for free. Entities concerned about monitoring for ''sole use'' may elect not to give away surgical (or any other) item, device, or supply. Moreover, items, devices, and supplies that do not constitute remuneration for purposes of the physician self-referral law may nonetheless implicate the anti-kickback statute.

Similarly, our clarification of the ''used solely'' requirement was not intended to loosen the requirement or to create a slippery slope that will lead to abusive arrangements. Prior to the proposed rule, we received inquiries from stakeholders questioning whether the mere fact that an item, device, or supply *could* be used for a purpose other than one or more of the permitted purposes means that the provision of such an item, device, or supply constitutes ''remuneration'' under our regulations. We are adding the phrase ''in fact'' to the definition to clarify that this is not the case and to provide certainty to parties regarding items, devices, or supplies with potential ancillary functions outside of one or more of the permitted purposes. At the same time, as indicated in our discussion of the provision of sterile gloves, we continue to believe that, for an item, device, or supply (including surgical tools) to satisfy the ''used solely'' requirement, the *primary purpose* of the item, device, or supply must be one or more of the uses permitted under the statute. Sterile gloves and other multi-use items, devices, or supplies whose primary purpose is not one of the permitted purposes are not excluded from the definition of ''remuneration,'' even if a particular physician in fact only uses the item, device, or supply for one of the permitted purposes. We do not disagree that it may be difficult for an entity to monitor how a physician ''in fact'' uses a multi-use item, device, or supply whose primary purpose is not one or more of the permitted purposes to ensure that the physician in fact uses the item, device, or supply exclusively for one or more of the permitted purposes. However, because the provision of multi-use items, devices, or supplies whose primary purpose is not one or more of the permitted purposes will not be carved out of the definition of remuneration.

We continue to believe that the Congress intended the carve-out at section 1877(h)(1)(C)(ii) of the Act to cover single-use items, devices, or supplies of low value that are primarily provided by laboratories to ensure proper collection of specimens. We note that, in the OBRA 1993 Conference Report, H.R. 103–213 pp. 818 through 819, the Congress characterized section 1877(h)(1)(C)(ii) of the Act as an ''exception'' for ''certain minor remuneration.'' Although we are not finalizing a monetary limit for the carve-out, we continue to believe that the items carved out of the definition of ''remuneration'' must be low value. We also reaffirm that the items, devices, or supplies provided to a physician must have little or no *independent* value to the physician. In this context, it is important to note that both the statute and our regulations provide that the items, devices, or supplies provided must serve a purpose *for the entity* providing the items, devices, or supplies; for example, collecting specimens *for the entity.* We believe that the phrase ''for the entity'' underscores that the items, devices, or supplies must have little, if any, independent value for the physician. Lastly, we emphasize that, even if the provision of an item, device, or supply is carved out of the definition of ''remuneration'' under the physician self-referral law, the provision of such items, devices, and supplies implicates the anti-kickback statute.

e. Transaction (and Isolated Financial Transaction)

Section 1877(e)(6) of the Act provides that an isolated financial transaction, such as a one-time sale of property or practice, is not a compensation arrangement for purposes of the physician self-referral law if: (1) The amount of remuneration under the transaction is consistent with the fair market value of the transaction and is not determined in a manner that takes into account (directly or indirectly) the

volume or value of referrals by the referring physician; (2) the remuneration is pursuant to an arrangement that would be commercially reasonable even if no referrals were made to the entity; and (3) the transaction meets any other requirements that the Secretary imposes by regulation as needed to protect against program or patient abuse. As enacted by OBRA 1989, the statutory exception identified a one-time sale of property as an example of an isolated financial transaction. In OBRA 1993, the Congress further clarified the statutory exception by providing an additional example of an isolated transaction, namely, a one-time sale of a practice. (*See* House Conference Report at H.R. Rep. No. 213, 103d Cong., 1st Sess. 813–815 (1993).)

In the 1992 proposed rule, we proposed an exception (ultimately codified at § 411.357(f)) to mirror the statutory exception at section 1877(e)(6) of the Act for certain isolated financial transactions (both titled and together referred to as the exception for isolated transactions) (57 FR 8591). In our proposal, we included a requirement—in addition to the statutory requirements—that there be no other transactions (that is, financial relationships) between the parties for 1 year before and 1 year after the financial transaction to ensure that financial transactions excepted under section 1877(e)(6) of the Act and § 411.357(f) are truly *isolated* in nature (57 FR 8599). In the 1995 final rule, we finalized an exception for isolated financial transactions at § 411.357(f), and we modified the proposed 1-year requirement in response to commenters that asserted that the requirement would create substantial and unnecessary problems (60 FR 41960). We stated that a transaction would be considered an isolated transaction for purposes of § 411.357(f) if there were no other transactions between the parties for 6 months after the transaction, except those transactions that are specifically excepted by another provision in §§ 411.355 through 411.357. We further stated that individual payments between parties generally characterize a compensation arrangement; however, debt, as described in the definition of ''ownership or investment interest'' at section 1877(a)(2) of the Act, can constitute an ownership interest that continues to exist until the debt is paid off (60 FR 41960). The 1995 final rule also established definitions of ''transaction'' and ''isolated transaction'' at § 411.351. We defined a ''transaction'' as an instance or process of two or more persons doing business and an ''isolated transaction'' as a transaction involving a single payment between two or more persons. The regulation at § 411.351 specified that a transaction involving long-term or installment payments is not considered an isolated transaction.

In the 1998 proposed rule, we proposed to revise the definition of ''transaction'' at § 411.351 to clarify that a transaction can involve persons *or* entities, but did not propose any substantive changes to the exception at § 411.357(f) (63 FR 1669). This definition was finalized in Phase II, with modification to permit installment payments (and post-closing adjustments) under certain circumstances (69 FR 16098). In Phase II, we also responded to commenters that objected to the prohibition on other transactions within 6 months of the excepted transaction. We declined to modify the 6-month prohibition on other transactions, and we explained that the concept of an *isolated* transaction is incompatible with the parties routinely engaging in multiple transactions in a year or during a short period of time. In Phase III, we made no changes to the exception at § 411.357(f), but updated the term ''isolated transaction'' at § 411.351 to refer to an ''isolated financial transaction,'' as that specific term is used in the statutory and regulatory exceptions (72 FR 51084).

Through our administration of the SRDP, work with our law enforcement partners, and interactions with stakeholders, it has come to our attention that some parties may believe that CMS' policy is that the exceptions in section 1877(e)(6) of the Act and § 411.357(f) for isolated transactions are available to protect service arrangements where a party makes a *single* payment for *multiple* services provided over an extended period of time. To illustrate, assume that a hospital makes a single payment to a physician for working multiple call coverage shifts over the course of a month (or several months) and seeks to utilize the exception at § 411.357(f) to avoid qualification of the payment as a financial relationship subject to the physician self-referral law's referral and billing prohibitions. That is, the parties wish to consider the single payment for multiple services an ''isolated financial transaction.'' We have observed that parties turn to the exception for isolated transactions to protect single payments for multiple services when they discover, typically after the services have been provided, that they failed to set forth the service arrangement in writing, and thus cannot rely on the exceptions for personal service arrangements or fair market value compensation. In fact, it is our policy that the exception for isolated transactions is *not* available to except payments for multiple services provided over an extended period of time, even if there is only a single payment for all the services. We see no reason to unduly stretch the meaning and applicability of the exception for isolated transactions beyond what was intended by the Congress. As described elsewhere in this final rule, our final regulations should facilitate compliance with the physician self-referral law in general and the writing and signature requirements in particular, including a 90-day period to reduce arrangements to a signed writing and an exception for limited remuneration to a physician. We believe that these final provisions will afford parties with sufficient flexibility to ensure that personal service and other compensation arrangements comply with the physician self-referral law.

To illustrate the kind of transactions that section 1877(e)(6) of the Act is meant to exempt, the Congress provided as examples a one-time sale of property and a one-time sale of a practice. In our view, a one-time sale of property or a practice is a unique, singular transaction. It is not possible for one party to repeatedly offer and sell the same property or medical practice to another party. In contrast, in service arrangements where multiple services are provided over an extended duration of time, the same services are provided on a repeated basis, even if there is only one payment for the multiple services provided. Also, in a one-time sale of property or a practice, the consideration for the transaction (that is, the transfer of ownership of the property or practice) is exchanged at the time payment is made in a single transaction (although § 411.357(f) permits installment payments under certain circumstances). In contrast, if a physician provides multiple services to an entity over an extended period of time, remuneration in the form of an in-kind benefit has passed repeatedly from the physician to the entity receiving the service prior to the payment date.

We remind parties that the provision of remuneration in the form of services commences a compensation arrangement at the time the services are provided, and the compensation arrangement must satisfy the requirements of an applicable exception *at that time* if the physician makes referrals for designated health services and the entity wishes to bill Medicare for such services. Thus, the exception for isolated transactions is not available

to retroactively cure noncompliance with the physician self-referral law. Our position is buttressed by the fact that the Congress created an exception for personal service arrangements at section 1877(e)(3) of the Act and required, among other things, that the arrangement is set out in writing and signed by the parties, that the term of the arrangement is at least 1 year, and that the compensation is set in advance. We do not believe that the Congress would impose such requirements for service arrangements under this exception, and then permit parties to avoid these requirements as long as the parties made one retrospective payment for multiple services provided over an extended period of time relying on the exception for isolated transactions.

After reviewing the comments, we are finalizing the proposed independent definition of ''isolated financial transaction'' at § 411.351, which clarifies that an ''isolated financial transaction'' does not include a single payment for multiple services provided over an extended period, with the following modifications: First, the final definition of ''isolated financial transaction'' specifies that an isolated transaction is a *one-time* transaction. Second, subparagraph (2) of the definition of ''isolated financial transaction'' at § 411.351 and the introductory chapeau language in § 411.357(f) provides as an additional example of an isolated financial transaction a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute. Third, we are clarifying at § 411.357(f)(4) that an isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute. Fourth, although we did not propose further changes to the definition of ''transaction'' at § 411.351, we are modifying the definition in response to comments to remove the phrase ''or process,'' because the term ''process'' has led some stakeholders to conclude that the exception is available to protect a single payment for multiple services provided over an extended period of time. Lastly, we are finalizing corresponding revisions to the exception for isolated transactions at § 411.357(f) to reference isolated *financial* transactions in order to align the exception text with the statutory provisions at section 1877(e)(6) of the Act. Even though the exception at § 411.357(f) applies to isolated *financial* transactions, we did not propose and we are not finalizing a change in the title of the exception from ''isolated transactions'' to ''isolated financial transactions,'' as the title of the statutory exception is ''isolated transactions.''

We received the following comments and our responses follow.

Comment: Many commenters expressed concern that, given the proposed definition of ''isolated financial transaction,'' the exception at § 411.357(f) would not apply to the settlement of a *bona fide* legal dispute, especially a dispute arising from an ongoing service arrangement, may not be excepted under § 411.357(f). Commenters noted that parties to a service arrangement may have a legitimate dispute concerning the amount of compensation due under a service arrangement, for example, where the terms of a contract documenting the arrangement are ambiguous. In these circumstances, a physician may have reasonable belief that he or she is owed more money under the contract, while the entity may believe in good faith that the physician is entitled to less than what the physician claims. Under such circumstances, the parties may wish to settle the matter to avoid litigation. The commenters expressed concern that the settlement could be construed as a single payment for multiple services previously provided by the physician and, therefore, the exception at § 411.357(f) would be unavailable to protect the compensation arrangement arising from the settlement payment (or reduction in debt). Several commenters maintained that resolution of a *bona fide* dispute is altogether different from making a single payment for multiple services provided over an extended period of time. The commenters requested that CMS expressly include a settlement of a *bona fide* legal dispute, along with a one-time sale of a property or practice, in the definition of ''isolated financial transaction,'' and strike language stating that an isolated financial transaction does not include a single payment for multiple services.

Response: Our policy has always been that the exception for isolated transactions at § 411.357(f) is applicable to a compensation arrangement arising from the settlement of a *bona fide* dispute, even if the dispute originates from a service arrangement where multiple services have been provided over an extended period of time. To clarify our longstanding policy, we are modifying the definition of ''isolated financial transaction'' at § 411.351 to include in subparagraph (2) a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, and we are including similar language in the introductory chapeau language at § 411.357(f). However, the exception is not applicable to the compensation arrangement that the parties dispute.

We agree with the commenters that stated that settlement of a *bona fide* dispute arising from an arrangement is fundamentally different from making a payment, including a single payment, for items or services provided under the arrangement. Although the settlement of a *bona fide* dispute may include a one-time payment made by a party (or installment payments as permitted under the exception), the cornerstone of a settlement of a *bona fide* dispute, as opposed to a payment for items or services, is that one or more of the parties forgoes a good faith claim to be paid more under the arrangement than the party actually receives. Therefore, we are describing the settlement of a *bona fide* dispute in the definition of ''isolated financial transaction'' and in the exception at § 411.357(f) as an instance of *forgiveness* of an amount owed. We are further clarifying at § 411.357(f)(4) that an isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute. Thus, a settlement of a *bona fide* legal dispute under § 411.357(f) is a separate compensation arrangement from any compensation arrangement between the parties giving rise to the *bona fide* dispute, and settlement of a *bona fide* dispute under § 411.357(f) does not retroactively bring the compensation arrangement that gave rise to the dispute into compliance with the physician self-referral law.

For the reasons explained above, we decline to omit from subparagraph (2) the phrase ''but does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated).'' Parties may rely on the exception at § 411.357(f) to protect an isolated financial transaction that settles a *bona fide* dispute arising from an arrangement for multiple, repeated, or ongoing services, but the exception is not available to protect a single payment for multiple or repeated services. A single payment for multiple or repeated services is not an isolated financial transaction, but rather an ongoing, extended compensation arrangement that must satisfy the requirements of another applicable exception.

Comment: Several commenters maintained that our proposal to exclude a single payment for multiple services from the definition of ''isolated financial transaction'' is inconsistent with the

statutory exception for isolated transactions at section 1877(e)(6) of the Act. According to the commenters' interpretation of section 1877(e)(6) of the Act, the statutory examples of isolated financial transactions, namely a one-time sale of property or a one-time sale of a practice, are illustrative only, and non-exhaustive. The commenters asserted that the exception may also be used for payments for services, noting that section 1877(e)(6) of the Act incorporates by reference certain requirements of the exception at section 1877(e)(2) of the Act for *bona fide* employment relationships, including the requirement that the remuneration is ''consistent with the fair market value of the *services*'' (emphasis added). Another commenter asserted that it is reasonable to see a single payment for items or services already furnished as an isolated transaction. The commenter provided as an example a hospital's single payment to a physician for fulfilling an unanticipated need for call coverage over a weekend or holiday, where the physician performs no others services for the hospital for the previous or subsequent 6-month periods.

Response: We agree with the commenters that the examples of isolated transactions in section 1877(e)(6) of the Act are illustrative only, not exhaustive. Among other things, as noted above, we believe that a single transaction resolving a *bona fide* dispute is an example of an isolated transaction that may be protected under the exception, if all the requirements of the exception are met. What the statutory examples illustrate, however, are *one-time* transactions, where there is not only a single payment (or installment payments as permitted under the exception) but also a single exchange of value, typically occurring on a specific date, involving consideration that is usually not the subject of repeated or frequent exchange over an extended period of time. In a sale of property or a practice, for example, there is typically a closing date when value is exchanged, and the parties ordinarily do not repeatedly transact to buy and sell the same property or practice over an extended period. The Congress' inclusion of the term ''one-time'' underscores that the exception is not available for transactions that are repeated over an extended period of time. In contrast to a one-time sale of property or a practice, if a physician repeatedly provides services to an entity over the course of months or years, then the physician has repeatedly provided remuneration to the entity in the form of an in-kind benefit during that timeframe. Even if the entity only makes one payment for the services, this is not a *one-time* transaction as contemplated by the statute, but rather an ongoing service arrangement. Because we interpret the exception for isolated transactions as protecting *one-time* transactions, as indicated at section 1877(e)(6) of the Act, we are modifying the definition of ''isolated financial transaction'' to include the term ''one-time.''

Under our interpretation of the statutory scheme, ongoing service arrangements, where a physician provides multiple services to an entity over an extended period of time, must satisfy all the requirements of another applicable exception, such as the exception for personal service arrangements at § 411.357(d)(1) or the exception for fair market value compensation at § 411.357(l). We do not believe that the Congress would have required ongoing service arrangements to meet all the requirements of section 1877(e)(3) of the Act, including writing, signature, 1-year term, and set in advance requirements, and then permit parties to sidestep these requirements by making a single, retrospective payment for multiple services relying on the exception for isolated transactions.

We agree with the commenters that not all service arrangements are *per se* excluded from protection under the exception for isolated transactions. In the proposed rule, we noted that the same services can be provided by one party and purchased by another on a repeated basis, whereas a party cannot repeatedly offer and sell the same property or medical practice to another party (84 FR 55808). We believe that the commenters may have inferred from this statement that our policy categorically excludes services from the isolated transaction exception. This is not our policy. As noted above, the exception for isolated transactions protects *one-time* transactions. With respect to an arrangement for services, the exception is available to protect a single payment (or installment payments, as permitted by the exception) for a *one-time* service arrangement, as opposed to an arrangement where multiple or repeated services are provided over an extended period of time. Whether a one-time service arrangement constitutes an isolated financial transaction depends on the facts and circumstances of the arrangement, including whether the service (or bundle of integrally related services) is provided in its entirety during a discrete time-period of short duration, such as a 24-hour or weekend shift. We note that, under § 411.357(f)(3), if parties utilize the exception for isolated transactions for a one-time service arrangement that qualifies as an isolated financial transaction, the parties would not be barred from entering into an ongoing arrangement for the same or similar services during the 6 months after the isolated financial transaction, provided that the subsequent service arrangement satisfied all the requirements of a different exception applicable to the subsequent service arrangement. The parties would, however, be barred from using the exception for isolated transactions for 6 months after the one-time service arrangement, regardless of the subject matter or consideration of the transaction.

Comment: Some commenters maintained that, under the plain language of the exception for isolated transactions and our previous guidance, the exception may be relied on to protect a single payment for multiple services. The commenters noted that ''transaction'' is currently defined to mean an ''instance or process'' of two or more persons or entities doing business, and stated that a ''process'' suggests an ongoing relationship such as an arrangement for repeated or multiple services provided over an extended period of time. The commenters further noted that the terms ''isolated financial transaction'' and ''transaction'' are defined together in the current regulations, and that ''isolated financial transaction'' is defined as a transaction involving a single payment. Another commenter objected to CMS' statement that the proposal is a clarification of longstanding policy and stated that there is nothing in the plain language of the exception to put parties on notice that the exception cannot be used to protect a single payment for multiple services.

Response: We first introduced the concept of a ''process'' of two or more persons doing business in the 1995 final rule (60 FR 41979). There is very little commentary in the 1995 final rule or subsequent rulemaking on the term ''process'' in the definition of ''transaction,'' though we did note in Phase II, when declining to adopt a policy allowing a certain number of transactions per year, that the concept of an isolated transaction is incompatible with parties routinely engaging in multiple transactions each year or more than one transaction during a short period of time (69 FR 16098). Moreover, in the FY 2009 IPPS final rule, we explained that all the requirements of an exception must be met at the time that a physician makes a referral, and that parties may not turn back the clock to retroactively ''cure'' noncompliant

arrangements (73 FR 48703). Under the statute and our regulations, a compensation arrangement is formed when remuneration, including in-kind remuneration such as the provision of a service, is exchanged between a physician and an entity. Thus, once a physician begins providing services to an entity under an arrangement, a compensation arrangement is formed, and the compensation arrangement must satisfy all the requirements of an exception at that time if the physician makes referrals to the entity. The statute and our previous policy statements in Phase II and the FY 2009 IPPS final rule are the basis for the policy articulated in the proposed rule and this final rule, namely that parties may not rely on the exception for isolated transactions to protect or retroactively ''cure'' a service arrangement involving the provision of multiple or repeated services over an extended period of time.

We recognize, however, that stakeholders may have been under the impression, given the use of the word ''process'' in the definition of ''transaction,'' that the exception for isolated transactions was available to protect service arrangements involving multiple or repeated services provided over an extended period of time. We also acknowledge that, under the current regulations, the definition of ''isolated financial transaction'' is subsumed under the definition of ''transaction,'' and, although the definition of ''isolated financial transaction'' requires a single payment (or installment payments, if certain requirements are met), it does not explicitly state that a single payment cannot be made for repeated or multiple services. To clarify our policy, we are deleting the term ''process'' from the definition of ''transaction'' in § 411.351 and we are explicitly stating in subparagraph (2) of the definition of ''isolated financial transaction'' at § 411.351 that an isolated financial transaction does not include a single payment for multiple or repeated services. We stress that these revisions are effective as of the date set forth in this final rule and apply prospectively only.

Comment: Many commenters maintained that our policy reduces flexibility and increases the burden of compliance with the physician self-referral law. The commenters noted that the exception for isolated transactions includes core safeguards of the physician self-referral law, such as requirements pertaining to fair market value, the volume or value of a physician's referrals and other business generated by the physician, and commercial reasonableness, and asserted that a single payment for multiple services that meets these requirements and the other requirements of § 411.357(f) does not pose a risk of program or patient abuse. One commenter stated that parties often seek to rely on the isolated transaction exception to make a single payment for items or service previously furnished, where the arrangement has not been documented before payment is made, and the documentation deficiencies are not discovered until after the items or services have been furnished (which may be for a period of more than 90 days).

Several commenters asserted that the proposal, if finalized, would have an especially acute impact on hospitals located in states that prohibit the corporate practice of medicine. According to the commenters, hospitals in states without such restrictions may rely on the exception for *bona fide* employment relationships for instances in which fair market value compensation has been paid to a physician for services provided, but the arrangement is not set out in writing and the compensation was not set in advance. The commenters noted that, in states where the employment of physicians is prohibited, the exception for *bona fide* employment relationships is not available, and the only available exception to protect the arrangement may be the exception for isolated transactions.

A few commenters, using identical language, provided an example of an arrangement that the commenters claimed should be covered by the exception for isolated transactions. In the example, an arrangement with an anesthesiology group is expiring, and despite good faith efforts to agree to the terms of a renewal arrangement, the parties disagree over the amount of compensation to be paid under the renewal. The commenters explained that the compensation formula in such a case may be very complex and take significant time to negotiate. In the commenters' example, the anesthesiology group agrees to keep providing services to patients after the previous arrangement expires while the parties continue to negotiate the terms of the renewal. The commenters contended that there is no harm to the Medicare program if, after the parties agree on compensation for the renewal, the entity relies on the exception for isolated transactions to compensate the physicians for services already furnished in the renewal term. The commenters suggested that no other exception would be available in this context, because the compensation for the renewal term was not set in advance of the services already provided, and the compensation would likely exceed the $3,500 limit under the proposed exception for limited remuneration to a physician.

Response: Our policy that the exception for isolated transactions is not available to protect a single payment for multiple or repeated services is grounded in our interpretation of the statute and the mandate under sections 1877(b)(4) and 1877(e)(6)(B) of the Act to protect only those financial relationships that do not pose a risk of program or patient abuse. We are not convinced that an ongoing service arrangement is an isolated financial transaction like a one-time sale of a property or a practice. Moreover, we do not believe that the Congress would have required an ongoing service arrangement to satisfy all the requirements of the exception for personal service arrangements at section 1877(e)(3) of the Act, including set in advance, writing, and 1-year term requirements, and allowed the same arrangement to be excepted under the exception for isolated transactions, which does not include these requirements. The commenters' example of the anesthesiology practice illustrates our concern with the use of the exception for isolated transactions to protect an ongoing service arrangement. As explained in section II.D.5 of this final rule, the ''set in advance'' requirement is an important safeguard to prevent parties from adjusting, including retrospectively adjusting, the compensation under an arrangement in a manner that takes into account the volume or value of a physician's referrals. In the commenters' example, the parties would be permitted to rely on the exception for isolated transactions to compensate the physicians retroactively, thus sidestepping the ''set in advance'' requirement of other exceptions and opening the door to adjustments of compensation during the negotiation period that take into account the volume or value of the physicians' referrals or other business generated by the physicians.

The special rule for writing and signature requirements at final § 411.354(e)(4) and the exception for limited remuneration to a physician at final § 411.357(z) provide significant flexibility under our regulations while providing sufficient safeguards, including an annual monetary limit of $5,000 (as adjusted for inflation) under § 411.357(z), a 90-day period for obtaining required writings under

§ 411.354(e)(4), and the requirement under § 411.354(e)(4) that the arrangement satisfy all the requirements of an applicable exception (other than the writing and signature requirement), including the ''set in advance'' requirement, for the first 90 days of the arrangement and thereafter. In contrast, the exception for isolated transactions does not limit the amount of compensation permissible under the arrangement, does not require the compensation arrangement to ever be in writing, and does not require compensation to be set in advance. Given the limited requirements of the exception for isolated financial transactions, we believe that excepting ongoing service arrangements under § 411.357(f), which could last for years and be worth hundreds of thousands of dollars or more, would pose a risk of program or patient abuse.

We note that, depending on the facts and circumstances, the parties in the commenters' example of an anesthesiology services arrangement could rely on the indefinite holdover provision at § 411.357(d)(1)(vii) to continue the arrangement on the same terms and conditions of the original arrangement while the parties negotiate the compensation terms for the renewal arrangement. Once the parties finalize the negotiations, compensation under the arrangement could be amended under new § 411.354(d)(1)(ii) (as discussed in section II.D.5. of this final rule) or the parties could enter into a new arrangement that satisfies the requirements of § 411.357(d)(1) or another applicable exception to the physician self-referral law. In either case, to meet the ''set in advance'' requirement, the newly negotiated compensation terms may only be applied *prospectively.*

Comment: A few commenters requested that, if CMS finalizes its proposed definition of ''isolated financial transaction,'' it should also finalize a new exception for isolated payments. The exception suggested by the commenters would permit an isolated, one-time payment for services already furnished, if: (1) The payment is consistent with fair market value and not determined in any manner that takes into account the volume or value of a physician's referrals or other business generated; and (2) the remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity. Similar to the current exception at § 411.357(f) for isolated transactions, there could be no additional exchanges of remuneration between the parties for 6 months after the isolated payment, except for financial relationships that satisfy all the requirements of another exception in § 411.355 through § 411.357. The commenters contended that their proposal incorporates the three central requirements of other compensation exceptions—fair market value compensation, commercial reasonableness of the arrangement, and compensation that is not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician—but would not require a writing or compensation set in advance.

Response: The exception suggested by the commenters does not differ substantively from the exception for isolated financial transactions at § 411.357(f). For the reasons explained in response to the immediately previous comment, adopting the commenters' suggestions would pose a risk of program or patient abuse and, therefore, we cannot issue the suggested exception under the authority at section 1877(b)(4) of the Act.

3. Denial of Payment for Services Furnished Under a Prohibited Referral—Period of Disallowance (§ 411.353(c)(1))

In the CY 2008 PFS proposed rule, we solicited comments on how to determine the period of time during which a physician may not make referrals for designated health services to an entity and the entity may not bill Medicare for the referred designated health services when a financial relationship between the parties failed to satisfy the requirements of any applicable exception (72 FR 38183). We referred to this timeframe as the ''period of disallowance.'' We stated that, as a general matter, the period of disallowance under the physician self-referral law should begin on the date when a financial relationship fails to satisfy the requirements of any applicable exception and end on the date that the financial relationship ends or is brought back into compliance (that is, satisfies all the requirements of an applicable exception). We noted, however, that it is not always clear when a financial relationship has ended. By way of example, we stated that, if a physician paid less than fair market value for the rental of office space, the below market rental payments may have been in exchange for future or anticipated referrals, so it is not clear if the financial relationship ended on the date that the lease expires. We sought comments on whether we should employ a case-by-case method for determining when a financial relationship ends or if we should, to the extent practicable, create a provision that would deem certain kinds of financial relationships to last a prescribed period of time for purposes of determining the period of disallowance. Assuming we were to prescribe a determinate amount of time for the period of disallowance in certain circumstances, we sought comments on whether the period of disallowance could be terminated if parties returned or repaid the value of any problematic compensation under an arrangement.

In the FY 2009 IPPS proposed rule, we proposed regulations at § 411.353(c)(1) pertaining to the period of disallowance (73 FR 23690 through 23692). Under that proposal, the period of disallowance would begin when the financial relationship failed to satisfy the requirements of any applicable exception. Where the noncompliance is unrelated to the payment of compensation, the period of disallowance would be deemed to end no later than the date that the financial relationship satisfies all the requirements of an applicable exception. Correspondingly, where the noncompliance is related to the payment of excess or insufficient compensation, we proposed that the period of disallowance would be deemed to end no later than the date on which the excess compensation was repaid or the additional required compensation was paid, and the arrangement satisfied all the requirements of an applicable exception. We emphasized that the proposal only prescribed an outside limit on the period of disallowance. We acknowledged that, in certain cases, a financial relationship may end before the excess compensation has been returned or the insufficient compensation paid in full, and that the period of disallowance in such cases would end when the financial relationship ended. However, we did not issue any regulations or guidance on determining when a financial relationship has ended in such cases, and we stated that the period of disallowance would have to be determined in such instances on a case-by-case basis. Lastly, we recognized that noncompliance may also arise for other reasons related to compensation, such as payments that take into account the volume or value of a physician's referrals, but we did not propose any regulations regarding how to determine the period of disallowance in such cases.

In the FY 2009 IPPS final rule, we finalized § 411.353(c)(1) as proposed, without substantive modifications (73 FR 48700 through 48705). We

emphasized again that the regulation only prescribed an outside date for the period of disallowance, and that parties could determine that the period of disallowance ended earlier than the outside date prescribed by the regulation on the theory that the financial relationship ended prior to this date. We made it clear in response to commenters that the period of disallowance established at § 411.353(c)(1) was not intended to extend the period of disallowance beyond the end of a financial relationship. Rather, the regulation was merely intended to give parties clear guidance on steps that could be taken to ensure that the period of disallowance had ended. In addition, we explained the application of the provisions regarding excess and insufficient compensation at § 411.353(c)(1)(ii) and (iii).

In the proposed rule, noting our experience administering the SRDP and stakeholder feedback that we have received over the years, we proposed to delete in their entirety the provisions setting forth the period of disallowance at § 411.353(c)(1) because we believe that, although the rules were initially intended merely to establish an outside, bright-line limit for the period of disallowance, in application, they appear to be overly prescriptive and impractical (84 FR 55809). We are finalizing this proposal. We emphasize that our action in this final rule does not permit parties to a financial relationship to make referrals for designated health services or to bill Medicare for the services when their financial relationship does not satisfy all the requirements of an applicable exception. It is a fundamental principle of the physician self-referral law that a physician may not make a referral for designated health services to an entity with which he or she (or an immediate family member) has a financial relationship, and the entity may not bill Medicare for the services, if the financial relationship between the parties does not satisfy all the requirements of an applicable exception. Nothing in this final rule affects the billing and referral prohibitions at § 411.353(a) and (b). We stress that the analysis to determine when a financial relationship has ended is dependent in each case on the unique facts and circumstances of the financial relationship, including the operation of the financial relationship as negotiated between the parties, and it is not possible for us to provide definitive rules that would be valid in all cases.

We also emphasize that removing the period of disallowance regulations is in no way meant to undermine parties who relied on § 411.353(c)(1)(ii) or (iii) in the past to establish that the period of disallowance has ended. The general principle stated in the CY 2008 PFS proposed rule that the period of disallowance under the physician self-referral law should begin on the date when a financial relationship fails to satisfy all the requirements of any applicable exception and end on the date that the financial relationship ends or satisfies all the requirements of an applicable exception remains true. And, we continue to believe that *one* way to establish that the period of disallowance has ended in such circumstances is to recover any excess compensation and bring the financial relationship back into compliance with the requirements of an applicable exception. However, we are aware that the payment of excess or insufficient compensation may complicate the question of when a financial relationship has ended or been brought back into compliance with the requirements of an applicable exception for purposes of the physician self-referral law, and believe that removing the period of disallowance regulations is the best way to ensure that what was intended as an elective ''safe harbor'' is not mistaken for a compulsory action required to ensure that the period of disallowance has ended.

As we stated in the proposed rule, since the publication of the FY 2009 IPPS final rule, stakeholders have questioned whether our preamble guidance was intended to state that administrative or other operational failures during the course of an arrangement, such as the erroneous payment of excess compensation or the erroneous failure to pay the full amount of compensation due during the timeframes established under the terms of an arrangement, would necessarily result in noncompliance with the physician self-referral law (84 FR 55809). Through submissions to the SRDP and other interactions with stakeholders, we are aware of questions regarding whether administrative errors, such as invoicing for the wrong amount of rental charges (that is, an amount other than the amount specified in the written lease arrangement) or the payment of compensation above what is called for under a personal service arrangement due to a typographical error entered into an accounting system, create the type of ''excess compensation'' or ''insufficient compensation'' described in our preamble guidance and the period of disallowance rules. As we stated in the proposed rule and affirm here, this was never our intent (84 FR 55809 through 55810). However, the failure to remedy such operational inconsistencies (that is, payment discrepancies) could result in a distinct basis for noncompliance with the physician self-referral law.

In the proposed rule, endeavoring to clarify statements in the FY 2009 IPPS final rule regarding whether parties can ''turn back the clock'' or retroactively ''cure'' noncompliance, we stated that parties that detect and correct administrative or operational errors or payment discrepancies *during* the course of the arrangement are not necessarily ''turning back the clock'' to address past noncompliance (84 FR 55811). Rather, it is a normal business practice, and a key element of an effective compliance program, to actively monitor ongoing financial relationships, and to correct problems that such monitoring uncovers. An entity that detects a problem in an ongoing financial relationship and corrects the problem while the financial relationship is still ongoing is addressing a current problem and is not ''turning back the clock'' to fix past noncompliance. On the other hand, once a financial relationship has ended, parties cannot retroactively ''cure'' the previous noncompliance by recovering or repaying problematic compensation. Of course, to the extent that the financial relationship has ended, the period of disallowance has ended as well. We believe this policy encourages active, regular review of arrangements for compliance with the physician self-referral law. We provided an example to illustrate our policy regarding payment discrepancies in the operation of a compensation arrangement (84 FR 55810 through 55811), and believe that it is useful to repeat the example from the proposed rule here. We have modified some of the language of the example for clarity.

Assume there is a 1-year arrangement between an entity and a physician beginning January 1 for the personal services of the physician; the arrangement is memorialized at the outset in a writing signed by the parties; the amount of compensation provided for in the writing does not exceed fair market value; and the arrangement otherwise fully complies with all the requirements of an applicable exception. Assume further that the entity provides compensation to the physician in months 1 through 6 in an amount other than what is stipulated in the writing, and the parties discover the payment discrepancy early in month 7. For purposes of this illustration, assume that a hospital pays a physician $150 per hour for medical director services

when the writing evidencing the arrangement between the parties identifies $140 per hour as the physician's rate of pay. If the $150 per hour payment is due to an administrative or other operational error—that is, the payment discrepancy was unintended—the parties may, while the arrangement is ongoing during the term initially anticipated (in this example, during the year of the arrangement), correct the error by collecting the overage (or making up the underpayment, if that is the case).

We expect entities and the physicians who refer designated health services to them to operate effective compliance programs that identify administrative or operational errors and rectify them promptly. We provided this example in the proposed rule and include it in this final rule to assure parties that unintended payment discrepancies that are corrected in a timely manner do not cause a compensation arrangement to fail to satisfy the requirements of an exception to the physician self-referral law during the timeframe of the erroneous operation of the arrangement. We did not state in the proposed rule, nor is it our view, that every error or mistake will cause a compensation arrangement to fail to satisfy the requirements of an exception or that every error or mistake must be corrected in order to maintain compliance with the physician self-referral law. However, if parties identify an error that would cause the compensation arrangement to fail to satisfy the requirements of an exception to the physician self-referral law, they cannot simply ''unring the bell'' by correcting it at some date after the termination of the arrangement. We discuss below the comments that we received regarding our statements in the proposed rule and this example.

In the proposed rule, we continued our analysis of the example provided, stating that, if the operational error—that is, payments of $150 per hour instead of the agreed upon $140 per hour—was not timely discovered and rectified, we would analyze the *actual* compensation arrangement between the parties as we would any financial relationship under the physician self-referral law. For purposes of explaining our policies in this final rule, assume also that the payments to the physician did not revert back to the intended $140 per hour for months 7 through 12, and the hospital did not recover any of the $10 per hour paid in excess of the intended $140 per hour. Therefore, the physician was, in fact, paid $150 per hour under the parties' arrangement for the provision of medical director services. In the proposed rule, we noted that the *actual* arrangement between parties does not always coincide with the terms described in the written documentation. To properly ascertain potential noncompliance, it is important to determine whether the *actual* amount of compensation paid under the arrangement—that is, the amount the physician actually received, as opposed to the amount stipulated in the written agreement—exceeded fair market value for the services actually provided. Assuming that the *actual* amount paid ($150 per hour) did not exceed fair market value and was not determined in any manner that took into account the volume or value of the physician's referrals or other business generated for the hospital, then the potential noncompliance would relate primarily to the failure to properly document the *actual* arrangement (medical director services compensated at $150 per hour) in writing, provided that the arrangement satisfied the remaining requirements of an applicable exception. We emphasize again in this final rule that various provisions in our regulations, including those finalized in this final rule, may offer parties a means of limiting the scope of potential noncompliance when the actions of the parties differ from their documented arrangement such that they create a separate compensation arrangement that must be analyzed for compliance with the physician self-referral law. To illustrate, assume the *actual* arrangement between the parties is for the provision of medical director services compensated at $150 per hour and all the requirements of an applicable exception are satisfied except for the requirements that the compensation is set in advance, in writing, and signed by the parties. The new exception finalized at § 411.357(z) for limited remuneration to a physician may be available to protect the first $5,000 paid to the physician (if the exception has not yet been utilized during the current calendar year). In addition, the parties could rely on the special rule for writing and signature requirements finalized at § 411.354(e)(3), coupled with the clarification of the writing requirement at § 411.354(e)(2), to establish that the actual amount of compensation provided under the arrangement was set forth in writing within 90 consecutive calendar days of the commencement of the arrangement via a collection of documents, including documents evidencing the course of conduct between the parties. The 90-day clock would begin when the parties could no longer use (or were no longer using) the exception at § 411.357(z). Thus, while the parties are relying on the exception at § 411.357(z) and for up to 90 consecutive calendar days after, they would likely be developing the documentation necessary to evidence their arrangement for medical director services under which the physician is paid $150 per hour. Depending on the facts and circumstances, the parties may be able to establish that the arrangement complied with the physician self-referral law for its entire duration.

Finally, as we stated in the proposed rule, in certain instances, the failure to collect money that is legally owed under an arrangement may potentially give rise to a secondary (separate) financial relationship between the parties (84 FR 55810). In such circumstances, because forgiveness of an obligation or debt may constitute remuneration for purposes of the physician self-referral law, the parties may conclude that the only means to avoid noncompliance with the physician self-referral law is to recoup the amount owed under the arrangement. Turning back to the previous example, and assuming that the hospital corrected the error beginning in month 7 but did not collect the excess compensation from the physician, the relevant inquiry is whether the uncorrected payment errors during months 1 through 6—that is, the additional $10 per hour paid to the physician—gave rise to a secondary financial relationship (for example, an interest free loan or the complete forgiveness of debt) that must satisfy the requirements of an applicable exception.

We received the following comments and our responses follow.

Comment: Commenters generally supported the removal of the ''period of disallowance'' provisions from § 411.353(c). One commenter stated that these provisions were cumbersome to apply and raised questions for parties deciding whether the period of disallowance ended. The commenter further stated that removal of the provisions will help parties to establish the end of the period of disallowance on a case-by-case basis without concern of having to defend why an arrangement is believed to have ended prior to the deeming provision in the regulations. One commenter agreed with our proposal, asserting that removing the period of disallowance regulations in their entirety would offer providers more flexibility to determine when a financial relationship has ended. In contrast, two commenters requested that we replace the period of disallowance regulation to provide for a date certain by which a compensation arrangement

would be deemed to end. Specifically, the commenters (in identical phrasing) suggested that the arrangement and, thus, the period of disallowance, should be deemed to end on the date that is 90 days after the physician (or immediate family member) last receives remuneration from the entity under the arrangement.

Response: As we stated in the proposed rule, although the period of disallowance provisions were initially intended to establish an outside, bright-line limit for the period of disallowance, the rules, in application, were overly prescriptive and impractical (84 FR 55809). We are finalizing our proposal to delete the provisions from § 411.353(c) of our regulations. We are not persuaded to establish a rule under which the period of disallowance would end 90 days after the physician (or immediate family member) last receives remuneration from the entity under the specific arrangement. Such a rule would be inappropriate in the case of remuneration to a physician that was substantially in excess of fair market value or that was determined in a manner that took into account the volume or value of the physician's referrals to the entity. In addition, the rule suggested by the commenters could extend the period of disallowance in many cases, for instance, in a case where a lease arrangement has ended and the noncompliance was related to the parties' failure to properly document it as required by our regulations. We believe that the determination of when the period of disallowance ends is best made on a case-by-case basis taking into consideration the facts and circumstances of the specific compensation arrangement between the parties.

Comment: Two commenters (in essentially identical comments) claimed that parties often have no way of knowing when certain types of compensation arrangements end. The commenters highlighted as particularly problematic one-time payments that are above or below fair market value and the provision of nonmonetary compensation in excess of the annual limit established in regulation. The commenter suggested that we adopt a rebuttable presumption that a compensation arrangement resulting from a one-time payment in excess or below fair market value or the payment of nonmonetary compensation above the annual limit in § 411.357(k)(1) ends the earlier of 6 months after the payment and the date the value causing the one-time payment or excess nonmonetary compensation is corrected (paid or repaid) by the physician (or the physician organization in whose shoes the physician stands under § 411.354(c)).

Response: One-time payments that are above or below fair market value may be an indication of a reward (that is, payment) for a physician's referrals. Referrals are not items or services (*see* section II.D.2.c. of this final rule); therefore, there is no exception available to protect the payment for referrals. A compensation arrangement that involves a one-time payment that is above or below fair market value does not lend itself to a one-size-fits-all approach. We decline to adopt the commenter's suggestion with respect to one-time payments that are above or below fair market value.

With respect to the provision of nonmonetary compensation in excess of the annual limit established in regulation, we offer the following observations. In Phase II, when explaining that the exception for temporary noncompliance does not apply to arrangements that previously complied with the exception for nonmonetary compensation at § 411.357(k), we noted that, in the case of nonmonetary compensation, it is possible to be compliant in the next year, since the exception permits nonmonetary compensation up to $300 annually (69 FR 16057). In Phase III, we clarified that the aggregate limit in § 411.357(k)(1) is to be calculated on a calendar year basis (72 FR 51058). Thus, on January 1 of the next calendar year, the parties would no longer be over the limit for the current calendar year. Put another way, the period of disallowance for nonmonetary compensation overages that are not repaid in accordance with § 411.357(k)(1) in most cases will end on December 31st of the year in which the excess nonmonetary compensation is provided. However, in rare instances, the period of disallowance may continue if the nonmonetary compensation is so valuable that it cannot fairly be considered the type of token of appreciation anticipated by the exception (72 FR 51059). For example, if a hospital gifts a physician an expensive new car on December 30th of a calendar year, the compensation arrangement that results from the transfer of the remuneration would not appropriately be considered to end the next day. Rather, the remuneration should be viewed as a likely exchange for the physician's future referrals. Under our final regulation at § 411.351, it is clear that referrals are not items or services for which an entity may provide remuneration. In essence, with respect to the provision of nonmonetary compensation that is not a fair market value exchange for items or services and the amount of which is over the annual limit at § 411.357(k)(1), there is a rebuttable presumption that the period of disallowance ends no later than December 31st of the year in which the excess nonmonetary compensation is provided. There is no need to adopt the commenter's suggestion with respect to the period of disallowance for the payment of excess nonmonetary compensation.

Comment: A large number of commenters expressed appreciation for our proposed rule guidance on remedying payment discrepancies that occur during the course of a compensation arrangement. Most of these commenters agreed that, if a party identifies an administrative or operational error or a payment discrepancy during the course of an arrangement, the parties do not fall out of compliance with the requirements of an applicable exception if the payment discrepancy is remedied prior to the end of the arrangement.

Response: As described more fully above and in our responses to other comments, an effective compliance program should enable parties to identify administrative and operational errors that result in payment discrepancies under a compensation arrangement. When payment discrepancies are identified and rectified in a timely manner, we do not believe that the discrepancies cause a compensation arrangement to be out of compliance with the requirements of the applicable exception during the time that they existed. We are codifying in regulation at new § 411.353(h) a special rule for reconciling compensation to confirm our policy view.

Comment: One commenter noted that, ideally, the impact of an effective compliance program will be the identification of payment discrepancies within the term of an arrangement, providing the parties an opportunity to cure the error. According to this commenter, however, even an effective compliance program may not identify all errors within the term of an arrangement. The commenter requested that CMS provide a grace period for correcting unintentional errors that would begin upon termination or expiration of an arrangement, expressing concern, along with other commenters, with a policy that does not allow for the correction of errors that are discovered after the termination or expiration of an arrangement. Some of these commenters asserted that it is unfair that errors discovered after several years of an ongoing multi-year arrangement could be corrected to ''right

the ship,'' while errors discovered even 1 week after the expiration of a 1-year arrangement could not. One commenter suggested that, provided that the parties to an arrangement correct any payment discrepancies within 1 year of the termination or expiration of an arrangement, we should consider the arrangement to have satisfied the requirements of the applicable exception for its entire duration. Other commenters asserted that ''retroactive curing'' of an arrangement (or ''turning back the clock'') should be permitted at any time.

Response: In Phase II, when we finalized the exception for temporary noncompliance at § 411.353(f), we stated that it was applicable in those instances where an arrangement has fully satisfied the requirements of another exception for at least 180 consecutive calendar days, but has fallen out of compliance with that exception for reasons beyond the control of the entity. We also stated that parties must take steps to rectify their noncompliance or otherwise comply with the statute as expeditiously as possible under the circumstances (69 FR 16057). In regulation, we provided that the period of time in which an entity must rectify the noncompliance must not exceed 90 consecutive calendar days. By the end of the 90-day exception period, parties must either comply with another exception or have terminated their otherwise prohibited financial relationship. We continue to believe in the importance of promptly rectifying noncompliance in those instances where the noncompliance occurs for reasons beyond the control of the entity. Our belief that parties should promptly reconcile known payment discrepancies that occur through their own administrative or operational errors in order to maintain compliance with the requirements of an exception is a logical extension of this policy. In Phase II, we also stated that the exception for temporary noncompliance is not intended to allow an entity to submit otherwise prohibited claims or bills when it purposefully takes or omits to take actions or engages in conduct that causes its financial relationship to be noncompliant with the requirements of an exception (69 FR 16057). It is our view that the knowing failure to comply with the terms of an arrangement negotiated by the parties is a purposeful or affirmative action or omission of the parties. It does not qualify as a reason beyond the control of the entity, and we are not persuaded by the commenters that we should allow a period of time for reconciliation of known payment discrepancies that exceeds the period for resolving temporary noncompliance occurring for reasons beyond the control of the entity. Specifically, permitting parties to reconcile payment discrepancies for a period of 1 year following the expiration or termination of their compensation arrangement or for an unlimited period of time would present a risk of program or patient abuse. Allowing a lengthy or unlimited period of time to correct payment discrepancies, especially in the case of significant payment discrepancies, would serve as a disincentive for parties to monitor arrangements for compliance with the physician self-referral law through an effective compliance program. Therefore, we decline to adopt the commenters' suggestions regarding the length of the reconciliation period. However, we are persuaded that a limited ''grace period'' to reconcile payment discrepancies following the expiration or termination of a compensation arrangement would not pose a risk of program or patient abuse. We believe that allowing the same period of time to reconcile payment discrepancies as the period to rectify noncompliance due to reasons beyond the control of the entity—but no longer—would not pose a risk of program or patient abuse. Therefore, we are finalizing at § 411.353(h) a special rule that permits an entity to submit claims or bills for designated health services and permits payment to be made to the entity for such designated health services if all payment discrepancies under the parties' arrangement (or the arrangement between the entity and the immediate family member of the physician) are reconciled within 90 consecutive calendar days of expiration or termination of the compensation arrangement, and following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement. To maintain consistency with other regulations that require remedial action within certain timeframes, the regulation specifies that the reconciliation must occur within the specified number of *consecutive calendar days.* Under the special rule for reconciling compensation at final § 411.353(h), if the parties to a compensation arrangement reconcile all payment discrepancies in the arrangement within this timeframe, the entity may submit a claim or bill and payment may be made to the entity for designated health services referred by the physician, assuming their arrangement satisfied all the requirements of an applicable exception during the entire duration of the arrangement, after considering the reconciliation.

Comment: One commenter asserted that a result of our policy that payment discrepancies reconciled during the course of an arrangement will prevent the arrangement from being considered out of compliance with the requirements of an exception to the physician self-referral law is that parties will continue arrangements they would otherwise wish to terminate in order to keep the arrangement ''live'' or ongoing so that identified payment discrepancies may be reconciled.

Response: The flexibility provided under the final special rule for reconciling compensation at § 411.353(h) should provide parties sufficient time to reconcile identified payment discrepancies without requiring the continuation of arrangements the parties no longer wish to have.

Comment: A few commenters asserted that it is unfair that parties could discover an error in the first few months of a long-term arrangement but not have to correct it until the end of the arrangement, yet parties that discover an error after the termination or expiration of an arrangement would be unable to take even immediate action to cure it in order to maintain compliance with the physician self-referral law.

Response: We believe the new special rule at § 411.353(h) addresses the latter part of the commenter's concern. However, the commenter's assumption that parties could discover an error in the first few months of a long-term arrangement and suffer no consequences under the physician self-referral law if they wait until the end of the arrangement to reconcile the discrepancies is incorrect. Although the new special rule for reconciling compensation at § 411.353(h) allows an entity to avoid violating the billing prohibition of the physician self-referral law if the parties reconcile all payment discrepancies under their arrangement within 90 consecutive calendar days following the expiration or termination of the arrangement, parties that fail to reconcile known payment discrepancies risk establishing a second financial relationship (for example, through the forgiveness of debt or the provision of an interest-free loan) that must satisfy the requirements of an applicable exception in order to avoid the prohibitions of the physician self-referral law. If the payment discrepancy or the failure to reconcile it (that is, recover excess compensation or collect

compensation owed) is significant enough to give rise to a separate financial relationship, that financial relationship must satisfy the requirements of an applicable exception once it exists. The commencement date of the second financial relationship depends on the facts and circumstances, such as the amount of excess compensation or unpaid compensation and how long the known overpayment or underpayment of the compensation has continued. For example, a large amount of excess compensation that is not recovered may give rise to a financial relationship in a shorter amount of time than a very small amount of unrecovered excess compensation or unpaid compensation. Thus, even if the entity is deemed not to have violated the physician self-referral law's billing prohibition once the original compensation arrangement is ultimately reconciled, the entity would be prohibited from submitting a claim or bill for a designated health service referred by the physician beginning at the point where the second financial relationship exists.

Comment: One commenter suggested that we allow parties an established amount of time after the end of a financial relationship to cure noncompliance with one or more requirements of an applicable exception. The commenter did not expressly limit its suggestions to payment discrepancies due to clerical errors or other unintentional deviation from the terms of a compensation arrangement. The commenter asserted that this approach would acknowledge the realities of the rhythms of compliance programs and recognize that it can take some time to identify, quantify, and cure defects in a financial relationship with a referring physician. The commenter claimed that this approach would not absolve an entity of its responsibility to structure its financial relationships with physicians to comply with the requirements of an applicable exception or to monitor its administration of those relationships.

Response: We are not adopting the commenter's suggestion to allow the correction of any aspect of a compensation arrangement that fails to satisfy the requirement of the exception upon which the parties rely. As we understand the commenter's suggested approach, parties would be able to retroactively restructure compensation arrangements that failed to satisfy the requirements of an applicable exception for any reason. This approach would allow parties to retroactively restructure compensation terms to comply with fair market value requirements or apply a different formula for the compensation so that it does not run afoul of the volume or value standard. To the extent the commenter was suggesting this approach only with respect to the types of errors we discussed in the proposed rule, we believe our final policy addresses the commenter's concerns.

Comment: One commenter requested clarification whether a hospital that has paid a physician excess compensation due to a technical error could ''cure'' the error by offsetting the amount to be recouped against future compensation over multiple years to alleviate hardship and navigate complex state employment laws related to wage recoupment and penalties charged to employees.

Response: The special rule for reconciling compensation at final § 411.353(h) requires that the reconciliation of payment discrepancies occurs no later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement. The commenter's inquiry relates to an ongoing compensation arrangement between the hospital and the physician. In such circumstances, the payment discrepancy could be recovered through an offset against future compensation. However, if the parties wish to ensure that their compensation arrangement is deemed to satisfy the requirements of an applicable exception throughout its entire duration, if their compensation arrangement expires or terminates before the entire amount of the payment discrepancy is recouped, the remaining amounts must be recouped within 90 consecutive calendar days following the expiration or termination of a compensation arrangement.

Comment: One commenter expressed concern with what it interpreted as a mandate for a party to recover any excess payments it has made in order to achieve compliance with the physician self-referral law. The commenter discussed the difficulty entities face when trying to recover excess payments or collect unmade payments from physicians and physician practices. The commenter explained that disputes over whether excess payments have been made or are owed are common and contribute to the difficulty entities face recovering excess payments or underpayments in order to achieve compliance. The commenter suggested that requiring the party to which money is owed to make a ''reasonable effort'' to be made whole would be sufficient, with the determination of ''reasonable effort'' dependent on the facts and circumstances of the arrangement, such as the amount of money at issue. The commenter asserted that, if a large amount of money is at issue, a reasonable effort might very well require a hospital, for example, to sue a physician or physician practice, but a lawsuit might not be reasonable for a dispute over a small amount of money or where the costs of the action would dwarf the amount owed. The commenter also asserted that a compromise of the amount owed may be justified if the physician or physician practice has equitable or legal defenses.

Response: As we explained in the proposed rule, the now-removed period of disallowance rules were never intended as anything more than deeming provisions so that parties could know the absolute latest date that the period of disallowance would end when the reason for the failure of their compensation arrangement to satisfy the requirements of an exception is the payment of excess compensation or the failure to pay all amounts due under the arrangement (84 FR 55809). The now-removed period of disallowance provisions never stated that a party must recover any excess payments it has made or recover any underpayment owed to it in order to achieve compliance with the physician self-referral law, nor do we adopt such a policy here. However, we reiterate the following points.

First, the new special rule for reconciling compensation arrangements permits the submission of a claim or bill and the payment of the claim or bill for a designated health service even if a compensation arrangement does not operate as intended with respect to its compensation terms, provided that: (1) No later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) that are parties to the compensation arrangement reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, all remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and (2) except for the discrepancies in payments described in paragraph (h)(1), the compensation arrangement fully complies with an applicable exception. This regulation assures an entity that its claims were not prohibited under section 1877(a)(1) of the Act or our regulations at § 411.353(b). However, it is a deeming provision only and does not require the entity to reconcile payment discrepancies.

Second, if payment discrepancies are not reconciled within 90 consecutive calendar days following the expiration

or termination of a compensation arrangement, the parties may not ''unring the bell'' on any noncompliance resulting from the payment discrepancies. In the event that the compensation arrangement failed to satisfy the requirements of an applicable exception due to discrepancies in payment as required under the terms and conditions of the arrangement, the period of noncompliance would begin at the time the payment discrepancies caused the arrangement to fail to satisfy the requirements of the exception. As described in response to other comments below, not all payment discrepancies necessarily result in noncompliance with the physician self-referral law.

Third, although recoupment of amounts due to payment discrepancies is not required to show that the period of disallowance has ended, referrals are prohibited and claims may not be submitted during the period that a financial relationship fails to satisfy the requirements of an applicable exception. If a physician was regularly paid more for services called for under an arrangement (due to an overpayment) or regularly paid less for items or services actually received (due to failure to pay all amounts owed), and the discrepancies were not reconciled during the course of the arrangement (or, under the policies finalized in this final rule, within 90 consecutive calendar days of the termination or expiration of the arrangement), from the point of the variance on, the arrangement would not satisfy the requirements of an applicable exception. Parties are free to demonstrate that a financial relationship has ended as they see fit. As always, in the absence of a financial relationship, the physician self-referral law is not implicated.

Fourth, we do not believe that ''reasonable efforts'' to recover excess payments or collect amounts due are equivalent to the reconciliation of payment discrepancies. A policy requiring that the parties make ''reasonable efforts'' would present compliance and enforcement challenges, and would not provide for the certainty that reduces burden on stakeholders. Moreover, we do not believe that the mere undertaking of ''reasonable efforts'' to recover excess payments or collect amounts due is sufficient to warrant a deeming provision allowing the submission of claims or bills for designated health services and the payment for such services where parties make ''reasonable efforts'' to recover excess payments or collect amounts due under their compensation arrangement.

Finally, as discussed in section II.D.2.e. of this final rule, parties to a legitimate dispute regarding a compensation arrangement may utilize the exception for isolated transactions at § 411.357(f) to protect the compensation arrangement that arises from the forgiveness of an obligation related to the settlement. However, the settlement of a dispute over payment discrepancies that confers remuneration on the party that is relieved of some or all of its obligation to refund excess payments or pay amounts due under the original arrangement does not retroactively return the original arrangement to compliance with the requirements of an exception.

Comment: A few commenters questioned our analysis that the *actual* activities and remuneration between parties constitutes the arrangement that must be analyzed for compliance with the physician self-referral law. These commenters argued that the ''arrangement'' is what the parties intended (as referenced in a written agreement or otherwise). The commenters also stated a belief that this position is unsupported by the statute. Another commenter asserted that, once the parties have memorialized in writing an arrangement that would satisfy the requirements of an applicable exception, if the arrangement satisfied all the requirements of an applicable exception at its inception, the referral and billing prohibitions of the physician self-referral law will not and cannot attach during the course of the arrangement.

Response: As we stated in Phase II and continue to believe, section 1877 of the Act is clearly intended to make entities responsible for monitoring their compensation arrangements with physicians (69 FR 16112). Unless a compensation arrangement between a physician (or immediate family member of a physician) and an entity satisfies the requirements of an applicable exception, section 1877 of the Act and § 411.353(a) and (b) of our regulations prohibit a physician from making a referral for designated health services and prohibit an entity from submitting a claim to Medicare or bill any individual, third party payor, or other entity for the designated health services furnished pursuant to a prohibited referral. As set forth in section 1877(h)(1) of the Act, the term ''compensation arrangement'' means any arrangement involving remuneration between a physician (or an immediate family member of such physician) and an entity. The regulation at § 411.354(c) specifies that the arrangement involving remuneration may be direct or indirect, but otherwise essentially incorporates the statutory definition. Neither of these definitions limits a compensation arrangement to that described in written documentation. Although many of the exceptions to the physician self-referral law require that the arrangement between the parties is documented in writing in order to avoid the law's prohibitions, the actions of the parties, regardless of what they have documented an arrangement to be, constitute the compensation arrangement between them.

The commenters assert that, once a compensation arrangement is documented in writing and satisfies the remaining requirements of an applicable exception, the referral and billing prohibitions of the physician self-referral law will not and cannot attach from that point forward and during the course of the arrangement, even if the parties deviate from the terms and conditions—including the payment terms and conditions—of the documented arrangement. If this were the case, parties would only need to document an arrangement that, on its face, would satisfy the requirements of an applicable exception. As noted, the physician self-referral law requires that, where a compensation arrangement exists between a physician (or an immediate family member of the physician) and the entity to which the physician makes referrals for designated health services, unless the compensation arrangement satisfies all the requirements of an applicable exception, the physician is prohibited from making referrals and the entity from submitting claims for designated health services. The physician self-referral law does not permit the physician to make referrals and the entity to submit claims for designated health services merely because an arrangement they documented would comply with the requirements of an applicable exception. The actions of the parties, regardless of what they have documented an arrangement to be, constitute the compensation arrangement between them. The commenter's assertion that the *actual* arrangement that exists between parties need not satisfy the requirements of an exception and the law's prohibitions would not apply as long as they have documentation of some arrangement they state they intended, if true, would reduce the statute to a paper tiger.

To be clear, for purposes of determining compliance with the physician self-referral law, the

arrangement under which the parties operate is analyzed to determine whether it satisfies all the requirements of an applicable exception. As discussed in the responses to other commenters, a slight deviation from the terms set forth in the written documentation of an arrangement may not result in a different *actual* arrangement between the parties.

Comment: Some commenters expressed concern with a policy under which—they assumed—even a single mistake, for instance if a check for single rental payment during an arrangement was written for the wrong amount, would turn the original arrangement into a different *actual* arrangement. One of these commenters stated its disagreement that a mere mistaken payment of remuneration creates a financial relationship within the meaning of the physician self-referral law, but conceded that, if an entity discovers that it has overpaid a physician or has been underpaid by a physician and fails to make reasonable efforts to recover the excess compensation or recover the shortfall, a new financial relationship in the form of a gift (that is, the forgiveness of debt) may arise, for which there would be no applicable exception under the physician self-referral law.

Response: We did not state in the proposed rule, nor is it our view, that every error or mistake will cause a compensation arrangement to fail to satisfy the requirements of an exception or that every error or mistake must be corrected in order to maintain compliance with the physician self-referral law. However, if parties identify an error that would cause the compensation arrangement to fail to satisfy the requirements of an exception to the physician self-referral law, they cannot simply ''unring the bell'' by correcting it at some date after the expiration or termination of the arrangement.

Given the individual commenter's concession that the failure to make reasonable efforts to recover excess compensation or a shortfall in payment may establish a new financial relationship in the form of a gift (that is, forgiveness of debt) for which there would be no applicable exception under the physician self-referral law, we assume that commenter's assertion that a mere mistaken payment of remuneration under a compensation arrangement does not create a second, separate financial relationship within the meaning of the physician self-referral law refers to the situation in which the parties never identify the mistaken payment (or underpayment) and are, therefore, unaware of the need to reconcile any payment discrepancies. We agree that not all transfers of remuneration create compensation arrangements. (*See* 66 FR 921 and 69 FR 16113.) In addition, theft generally does not create a compensation arrangement between the thief and the victim. For example, the theft of items, the use of office space that is not included in a lease, and the use of equipment during periods outside those included in a lease would not create a compensation arrangement between the party whose assets have been coopted and the party that took them or used them without permission or payment. Further, a slight deviation from the operation of the arrangement as anticipated and documented (where written documentation is required under the applicable exception) that results in the payment of too much or too little compensation under an arrangement—for example, in the case of a single rental payment over the course of an entire lease arrangement that was paid in the wrong amount—may not require reconciliation by the party receiving the overpayment or failing to make the full payment due, especially if the parties are not aware of the discrepancy. However, where a party is aware of the mistakes (or payment discrepancies) in the operation of its arrangements, as the commenter stated, the failure to correct the mistake may indeed establish a second financial relationship between the parties, depending on the facts and circumstances.

4. Ownership or Investment Interests (§ 411.354(b))

a. Titular Ownership or Investment Interest (§ 411.354(b)(3)(vi))

In the FY 2009 IPPS final rule, we introduced the concept of titular ownership or investment interests in the context of our rulemaking pertaining to the ''stand in the shoes'' provisions at § 411.354(c) (73 FR 48693 through 48699). Under the provisions finalized in the FY 2009 IPPS final rule, for purposes of determining whether a compensation arrangement between an entity and a physician organization is deemed to be a compensation arrangement between the entity and the physician owners, employees, and contractors of the organization, a physician whose ownership or investment interest in the physician organization is merely titular in nature is not required to stand in the shoes of the physician organization (73 FR 48694). We explained that an ownership or investment interest is considered to be ''titular'' if the physician is not able or entitled to receive any of the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment (73 FR 48694). The concept of titular ownership or investment interests set forth in the FY 2009 IPPS final rule applied only to the stand in the shoes provisions at § 411.354(c) which pertain to compensation arrangements. Because we were responding to a comment on the 1998 proposed rule (and the Phase I comments thereafter) regarding the application of the exceptions for compensation arrangements, we did not propose to extend the concept of titular ownership or investment interests to the provisions at § 411.354(b) pertaining to ownership or investment interests. Separately, we had previously concluded in a 2005 advisory opinion (CMS–AO–2005–08–01) that, for purposes of section 1877(a) of the Act, physician-shareholders of a group practice who did not receive any of the purchase and ownership rights or financial risks and benefits typically associated with stock ownership would not be considered to have an ownership or investment interest in the group practice.

In the proposed rule, we proposed to extend the concept of titular ownership or investment interests to our rules governing ownership or investment interests at § 411.354(b). We explained that, under proposed § 411.354(b)(3)(vi), ownership and investment interests would not include titular ownership or investment interests. Consistent with the FY 2009 IPPS final rule, a ''titular ownership or investment interest'' would be an interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment. As noted in the FY 2009 IPPS final rule, whether an ownership or investment interest is titular is determined by whether the physician has any right to the financial benefits through ownership or investment (73 FR 48694). We are finalizing § 411.354(b)(3)(vi) as proposed. The new regulation at § 411.354(b)(3)(vi) should afford providers and suppliers with greater flexibility and certainty under our regulations, especially in states where the corporate practice of medicine is prohibited. For the reasons similar to those stated in our advisory opinion CMS–AO–2005–08–01, namely that a physician with a titular ownership in an entity does not have a

right to the distribution of profits or the proceeds of sale and, therefore, does not have a financial incentive to make referrals to the entity in which the titular ownership or investment interest exists, our interpretation and revised definition of ''ownership or investment interest'' does not pose a risk of program or patient abuse. We are finalizing § 411.354(b)(3)(vi) as proposed, without modification.

We received the following comment and our response follows.

Comment: Nearly all the commenters that addressed the proposal to revise § 411.354(b)(3) supported excluding titular ownership from qualifying as an ownership or investment interest under § 411.354(b). One commenter emphasized that the proposal, if finalized, would afford physicians with greater flexibility, especially in States where the corporate practice of medicine is prohibited.

Response: We have long recognized that an interest in an entity that excludes the ability or right to receive the financial benefits of ownership should not be considered to constitute an ownership or investment interest for purposes of the physician self-referral law. (*See* CMS advisory opinion CMS–AO–2005–08–01.) Our proposal at § 411.354(b)(3)(vi) codifies this policy. The policy we are explicitly articulating in regulatory text at § 411.354(b)(3)(vi) will provide stakeholders greater certainty under our regulations. We caution that any compensation arrangement between a physician and an entity in which the physician or an immediate family member of the physician holds only a titular ownership or investment interest must nonetheless satisfy all the requirements of an applicable exception in § 411.355 or § 411.357.

b. Employee Stock Ownership Program (§ 411.354(b)(3)(vii))

We stated in the 1998 proposed rule that an interest in an entity arising through a retirement fund constitutes an ownership or investment interest in the entity for purposes of section 1877 of the Act (63 FR 1708). Our interpretation was based on the premise that a retirement interest in an entity creates a financial incentive to make referrals to the entity. In Phase I, we reconsidered the issue and withdrew the statement regarding retirement interests that we made in the 1998 proposed rule (66 FR 870). As finalized in Phase I, § 411.354(b)(3)(i) excluded an interest in a retirement plan from the definition of ''ownership or investment interest.'' We stated that retirement contributions, including contributions from an employer, would instead be considered to be part of an employee's overall compensation.

We made no changes to § 411.354(b)(3)(i) in Phase II. However, after publishing Phase II, we received a comment stating that, contrary to our intent, some physicians were using their retirement plans to purchase or invest in other entities (that is, entities other than the entity that sponsored the retirement plan) to which the physicians were making referrals for designated health services. We made no changes to § 411.354(b)(3)(i) in Phase III, but proposed in the CY 2008 PFS proposed rule to address the potential abuse described by the commenter on Phase II (72 FR 38183). After reviewing the comments received in response to that proposal, in the FY 2009 IPPS final rule, we finalized changes to § 411.354(b)(3)(i) that restricted the retirement interest carve-out to an interest in an entity that arises from a retirement plan offered by the entity to the physician (or an immediate family member) through the physician's (or immediate family member's) employment with that entity (73 FR 48737 through 48738). Under the current regulation at § 411.354(b)(3)(i), if, through his or her employment by Entity A, a physician has an interest in a retirement plan offered by Entity A, any interest the physician may have in Entity A by virtue of his or her interest in the retirement plan would not constitute an ownership or investment interest for purposes of section 1877 of the Act. On the other hand, if the retirement plan sponsored by Entity A purchased or invested in Entity B, the physician would have an interest in Entity B that would not be excluded from the definition of ''ownership or investment interest'' for purposes of the physician self-referral law. For the physician to make referrals for designated health services to Entity B, the ownership or investment interest in Entity B would have to satisfy the requirements of an applicable exception. We explained in the FY 2009 IPPS final rule that it would pose a risk of program or patient abuse to permit a physician to own another entity that furnishes designated health services (other than the entity which employs the physician) through his or her retirement plan, because the physician could then use the retirement interest carve-out to skirt the prohibitions of the physician self-referral law (73 FR 48737 through 48738).

Since we published the 2009 IPPS final rule, stakeholders have informed us that, in certain cases, employers seeking to offer retirement plans to physician employees may find it necessary or practical, for reasons of Federal law, State law, or taxation, to structure a retirement plan using a holding company. By way of example, assume a home health agency desires to sponsor a retirement plan for its employees and elects to establish such plan using a holding company whose primary asset will be the home health agency. To effectuate the retirement plan, the home health agency's assets are transferred to or purchased by the holding company, which then employs the physicians and other staff of the home health agency. The holding company sponsors the retirement plan for its employees, offering the employees (including physician employees) an interest in the holding company. Under our current regulation at § 411.354(b)(3)(i), the physician's interest in the holding company would not be considered an ownership or investment interest, because the physician is employed by the holding company, the holding company sponsors the retirement plan, and the physician's ownership interest in the holding company arises through the retirement plan sponsored by the holding company. However, because the physician has an interest in the retirement plan that owns the holding company, and the holding company owns the home health agency, the physician has an indirect ownership or investment interest in the home health agency that would not be excluded under § 411.354(b)(3)(i) and may not satisfy the requirements of an applicable exception at § 411.356.

It is our understanding that a retirement plan structure involving ownership of a holding company and indirect ownership of a legally separate entity (as defined at § 411.351) may be particularly advantageous or necessary in certain circumstances for the establishment of an employee stock ownership plan (ESOP). An ESOP is an individually designed stock bonus plan, which is qualified under Internal Revenue Code (IRC) section 401(a), or a stock bonus and a money purchase plan, both of which are qualified under IRC section 401(a), and which are designed to invest primarily in qualifying employer securities. It is our understanding that ESOPs must be structured to comply with certain safeguards under the Employee Retirement Income Security Act of 1974 (ERISA) (Pub. L. 93–406), including certain nondiscrimination rules and vesting rules that, among other things, do not allow an employee to receive the value of his or her employer stocks held

through the retirement plan until at least 1 year after separation from the employer. Given the statutory and regulatory safeguards that exist for ESOPs, we believe that an interest in an entity arising through participation in an ESOP merits the same protection from the physician self-referral law's prohibitions as an interest in an entity that arises from a retirement plan offered by that entity to the physician through the physician's employment with the entity. We do not believe that excluding from the definition of ''ownership or investment interest'' an interest in an entity that arises through participation in an ESOP qualified under IRC section 401(a) poses a risk of program or patient abuse, and we are finalizing our proposal at § 411.354(b)(3)(vii) to remove such interests from the definition of ''ownership or investment interest'' for purposes of section 1877 of the Act. To provide regulatory flexibility in structuring retirement plans, § 411.354(b)(3)(vii) is not restricted to an interest in an entity that both employs the physician and sponsors the retirement plan.

To illustrate our policy, assume that a holding company is owned by its employees, including physician employees, through an ESOP, and that the holding company owns a separate legal entity that furnishes designated health services (an ''entity'' for purposes of section 1877 of the Act). Under § 411.354(b)(3)(vii), for purposes of the physician self-referral law, the physician's interest in the ESOP will not constitute an ownership or investment interest in the holding company or the legally separate entity the holding company owns. As with the current retirement interest exclusion at § 411.354(b)(3)(i), employer contributions to the ESOP on behalf of an employed physician will be considered part of the physician's overall compensation and will have to meet the requirements of an applicable exception for compensation arrangements at § 411.357 or the physician's individual referrals must satisfy the requirements of an applicable exception in § 411.355.

In the proposed rule, we sought comments on whether the safeguards that are imposed by ERISA are sufficient for purposes of the physician self-referral law to ensure that an ownership or investment interest in an ESOP does not pose a risk of program or patient abuse and, if not, what additional safeguards we should include to ensure that such interests do not pose a risk of program or patient abuse. To prevent the kind of abuses identified by the commenter on Phase II, we sought comment as to whether it is necessary to restrict the number or scope of entities owned by an ESOP that would not be considered an ownership or investment interest of its physician employees. It is our understanding that an ESOP is designed to invest primarily in ''qualifying employer securities,'' but the ESOP may also invest in other securities. We sought comment on whether the exclusion from the definition of ''ownership or investment interest'' should apply only to an interest in an entity arising from an interest in ''qualifying employer securities'' that are offered to a physician as part of an ESOP. Finally, we sought comment on whether the revision to § 411.354(b)(3)(vii) is necessary; that is, whether existing § 411.354(b)(3)(i) affords entities furnishing designated health services sufficient regulatory flexibility to structure nonabusive retirement plans, including ESOPs or other plans that involve holding companies (84 FR 55812).

We are finalizing § 411.354(b)(3)(vii) as proposed, without modification.

We received the following comment and our response follows.

Comment: Nearly all the commenters that addressed the proposal at § 411.354(b)(3)(vii) favored excluding an interest in an entity that arises by virtue of a physician's participation in an ESOP from the regulation regarding what constitutes an ownership or investment interests under § 411.354(b). Commenters stated that no additional safeguards or requirements are necessary. Two commenters pointed to specific safeguards related to ESOPs that are imposed by ERISA, which they asserted are sufficient to protect against program or patient abuse. One of the commenters highlighted that ERISA requires a fiduciary to act with care, skill, prudence, and diligence under the circumstances of a prudent person acting in a similar capacity, and ESOPs are required to have an independent appraiser to establish value for all securities which are not readily tradable on a market. The other commenter emphasized that ESOPs are also regulated by the U.S. Department of Treasury. This commenter highlighted anti-abuse rules for ESOPs in section 409(p) of the Internal Revenue Code, which mandate broad-based employee ownership and establish strict repercussions for violations. According to this commenter, since their enactment, these rules have been highly effective in ensuring that ESOPs serve their intended purpose and are not subject to abuse.

Response: We are convinced by the commenters that the legal and regulatory protections applicable to ESOPs are sufficient to prevent program or patient abuse, and we are finalizing § 411.354(b)(3)(vii) without any additional requirements. We remind parties that employer contributions to the ESOP are considered part of an employee's overall compensation arrangement with his or her employer (*see* 66 FR 870). Thus, when determining whether a compensation arrangement satisfies all the requirements of an applicable exception, including the requirements pertaining to fair market value and the volume or value of the physician's referrals, employer contributions to the ESOP must be considered as part of the employee's compensation under the arrangement.

5. Special Rules on Compensation Arrangements (§ 411.354(e))

In the CY 2008 PFS proposed rule, we proposed an alternative method for satisfying certain requirements of some of the exceptions in §§ 411.355 through 411.357 (72 FR 38184 through 38186). We explained that, although we do not have the authority to waive violations of the physician self-referral law, we do have the authority under section 1877(b)(4) of the Act to implement an alternative method for satisfying the requirements of an exception. The proposed method would have required, among other things, that an entity self-disclose the facts and circumstances of the arrangement at issue and that CMS make a determination that the arrangement satisfied all but the ''procedural or 'form' requirements'' of an exception (72 FR 38185). We cited the signature requirement of the exception for personal service arrangements at § 411.357(d)(1) as an example of a procedural or ''form'' requirement, and explained that the alternative method would not be available for violations of requirements such as compensation that is fair market value, set in advance, and not determined in any manner that takes into account the volume or value of a physician's referrals.

In the FY 2009 IPPS final rule, we did not finalize the alternative method proposed in the CY 2008 PFS proposed rule. Instead, relying on our authority under section 1877(b)(4) of the Act, we finalized a rule for temporary noncompliance with signature requirements at § 411.353(g) (73 FR 48705 through 48709). As finalized in the FY 2009 IPPS final rule, § 411.353(g) applied only to the signature requirement of an applicable exception

in § 411.357. We declined to extend the special rule for temporary noncompliance to any other procedural or ''form'' requirement of an exception (73 FR 48706) or to noncompliance arising from ''minor payment errors'' (73 FR 48703). The special rule at § 411.353(g) permitted an entity to submit a bill and receive payment for a designated health service if the compensation arrangement between the referring physician and the entity fully complied with the requirements of an applicable exception at § 411.357, except with respect to the signature requirement, and the parties obtained the required signatures within 90 consecutive calendar days if the failure to obtain the signatures was inadvertent, or within 30 consecutive calendar days if the failure to obtain the signatures was not inadvertent (73 FR 48706). Entities were allowed to use the special rule at § 411.353(g) only once every 3 years with respect to the same physician. We stated that we would evaluate our experience with the special rule at § 411.353(g) and that we may propose modifications, either more or less restrictive, at a later date (73 FR 48707). Subsequently, in the CY 2016 PFS final rule, we removed the distinction between failures to obtain missing signatures that were inadvertent and not inadvertent, thereby allowing all parties up to 90 consecutive calendar days to obtain the missing signatures (80 FR 71333). As discussed in further detail in this section of the final rule, following a revision to section 1877 of the Act, in the CY 2019 PFS final rule, we removed the provision limiting the use of the special rule at § 411.353(g) to once every 3 years with respect to the same physician (83 FR 59715 through 59717).

In the CY 2016 PFS final rule, we clarified that the writing requirement of various exceptions in § 411.357 can be satisfied with a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties (80 FR 71314 through 71317).[11] In response to our proposals regarding satisfaction of the writing requirement, one commenter requested that CMS permit a 60- or 90-day grace period for satisfying the writing requirement of an applicable exception, stating that such a grace period is needed for last minute arrangements between physicians and entities to which they refer patients for designated health services (80 FR 71316 through 71317). In response, we noted that the special rule at § 411.353(g) applied only to temporary noncompliance with the signature requirement of an applicable exception, and we declined to extend the special rule to the writing requirement of various exceptions at § 411.357. We stated that a ''grace period'' for satisfying the writing requirement could pose a risk of program or patient abuse; for example, if the rate of compensation is not documented before a physician provides services to an entity, the entity could adjust the rate of compensation during the grace period in a manner that takes into account the volume or value of the physician's referrals (80 FR 71317). We added that an entity could not satisfy the set in advance requirement at the outset of an arrangement if the only documents stating the compensation term of an arrangement were generated after the arrangement began. Finally, we reminded parties that, even if an arrangement is not sufficiently documented at the outset, depending on the facts and circumstances, contemporaneous documents created during the course of an arrangement may allow parties to satisfy the writing requirement and the set in advance requirement for referrals made *after* the contemporaneous documents were created (80 FR 71317).

Section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) (BiBA) added provisions to section 1877(h)(1) of the Act pertaining to the writing and signature requirements in certain exceptions applicable to compensation arrangements. As amended, section 1877(h)(1)(D) of the Act provides that the writing requirement in various exceptions applicable to compensation arrangements ''shall be satisfied by such means as determined by the Secretary,'' including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. Section 1877(h)(1)(E) of the Act created a statutory special rule for temporary noncompliance with signature requirements, providing that the signature requirement of an applicable exception shall be satisfied if the arrangement otherwise complies with all the requirements of the exception and the parties obtain the required signatures no later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant. In the CY 2019 PFS final rule, we finalized at § 411.354(e) a special rule on compensation arrangements, which codified in our regulations the clarification of the writing requirement found at section 1877(h)(1)(D) of the Act (83 FR 59715 through 59717). In addition, we removed the 3-year limitation on the special rule on temporary noncompliance with signature requirements at § 411.353(g)(2) in order to align the regulatory provision at § 411.353(g) with section 1877(h)(1)(E) of the Act. We proposed, in the alternative, to delete § 411.353(g) in its entirety and to codify section 1877(h)(1)(E) of the Act in the newly created special rules on compensation arrangements at § 411.354(e). However, we declined to finalize the alternative proposal in the CY 2019 PFS final rule, because we believed it would be less disruptive to stakeholder compliance efforts to amend already-existing § 411.353(g).

As stated in our proposed rule, we have reconsidered our policy on temporary noncompliance with the signature and writing requirements of various compensation arrangement exceptions (84 FR 55813 through 55814). In our administration of the SRDP, we have reviewed numerous compensation arrangements that fully satisfied all the requirements of an applicable exception, including requirements pertaining to fair market value compensation and the volume or value of referrals, except for the writing or signature requirements. In many cases, there are short periods of noncompliance with the physician self-referral law at the outset of a compensation arrangement, because the parties begin performance under the arrangement before reducing the key terms and conditions of the arrangement to writing. As long as the compensation arrangement otherwise meets all the requirements of an applicable exception, and the parties memorialize the arrangement in writing and sign the written documentation within 90 consecutive calendar days, we do not believe that the arrangement poses a risk of program or patient abuse. Therefore, it is appropriate to provide entities and physicians flexibility under our rules to satisfy the writing or signature requirement of an applicable exception within 90 consecutive calendar days of the inception of a compensation arrangement.

Relying on our authority at section 1877(h)(1)(D) of the Act, which grants the Secretary the authority to determine the means by which the writing requirement of a compensation arrangement exception may be satisfied, and section 1877(h)(1)(E) of the Act,

[11] Our guidance on the writing requirement was subsequently codified in statute in section 1877(h)(1)(D) of the Act and incorporated into our regulations at § 411.354(e). *See* 83 FR 59715 through 59717.

which establishes a statutory rule for temporary noncompliance with signature requirements, we proposed to create a special rule for noncompliance with the writing or signature requirement of an applicable exception for compensation arrangements. Specifically, we proposed to delete § 411.353(g) in its entirety, codify the statutory rule for noncompliance with signature requirements at section 1877(h)(1)(E) of the Act in a special rule on compensation arrangements at § 411.354(e)(3), and incorporate a special rule for noncompliance with the writing requirement into the new special rule at § 411.354(e)(3). In this final rule, the special rule on writing and signature requirements is designated as § 411.354(e)(4) and a new rule on electronic signatures is included in our regulations at § 411.354(e)(3).

Under the special rule for writing and signature requirements at § 411.354(e)(4), the writing requirement or the signature requirement is deemed to be satisfied if: (1) The compensation arrangement satisfies all the requirements of an applicable exception other than the writing or signature requirement(s); and (2) the parties obtain the required writing or signature(s) within 90 consecutive calendar days immediately after the date on which the arrangement failed to satisfy the requirement(s) of the applicable exception. A party may rely on § 411.354(e)(4) if an arrangement is neither in writing nor signed at the outset, provided both the required writing and signature(s) are obtained within 90 consecutive calendar days and the arrangement otherwise satisfied all the requirements of an applicable exception. We remind readers that, as we explained in the CY 2016 PFS final rule and subsequently codified at § 411.354(e)(2), a single formal written contract is not necessary to satisfy the writing requirement in the exceptions to the physician self-referral law (80 FR 71314 through 71317). Depending on the facts and circumstances, the writing requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. Thus, parties to an arrangement would have 90 consecutive calendar days to compile the collection of documents if the parties determine to show compliance with the writing requirement in this manner. We note that, because parties must compile the documents that evidence their arrangement within 90 consecutive calendar days of the commencement of the arrangement, if an arrangement expires or is terminated before the compilation is complete or the end of the ''grace period,'' whichever comes first, the parties may not rely on the special rule at § 411.354(e)(4) to establish compliance with the physician self-referral law for their arrangement. However, depending on the facts and circumstances, the new exception for limited remuneration to a physician at § 411.357(z), which does not include a writing or signature requirement, might be available to protect a short-term arrangement.

We stressed in the proposed rule and reiterate here that our proposal to permit parties up to 90 consecutive calendar days to satisfy the writing requirement of an applicable exception does not amend, nor does it affect, the requirement under various exceptions in § 411.357 that compensation must be set in advance. The amount of or formula for calculating the compensation must be set in advance and the arrangement must satisfy all other requirements of an applicable exception, other than the writing or signature requirements, in order for parties to an arrangement to establish compliance with the physician self-referral law by relying on § 411.354(e)(4). Section 1877(h)(1)(D) of the Act provides the Secretary with the authority to determine the means by which the writing requirement may be satisfied, but it does not provide the Secretary similar authority with respect to the set in advance requirement. Moreover, we believe that the set in advance requirement is necessary to prevent parties from retroactively adjusting the amount of compensation paid under an arrangement in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician over the course of the arrangement, including the first 90 days of the arrangement.

In the proposed rule, we did not propose to amend the special rule on compensation that is considered to be set in advance at § 411.354(d)(1), though we did clarify that § 411.354(d)(1) is a deeming provision, not a requirement (84 FR 55782). As explained in more detail below, in response to comments, we are finalizing certain modifications to the special rule at § 411.354(d)(1), including codifying *requirements* at § 411.354(d)(1)(ii) for modifying the compensation (or formula for determining the compensation) during the course of an arrangement. The new regulation related to modifying compensation terms during the course of an arrangement requires that the modified compensation (or formula for determining compensation) is set out in writing before the furnishing of items or services for which the modified compensation is to be paid, and it specifically provides that parties do not have 90 days under § 411.354(e)(4) to reduce the modified compensation terms to writing. We emphasize that the requirements in new § 411.354(d)(1)(ii), including the writing requirement, apply only when the parties *modify* the compensation (or formula for determining compensation) during the course of an arrangement.

In this final rule, the current special rule at § 411.354(d)(1) is redesignated as § 411.354(d)(1)(i). To underscore that this rule is merely an optional ''deeming provision'' and not a requirement, we are replacing the phrase ''is considered 'set in advance' '' with ''is deemed to be 'set in advance'.'' We are also deleting the phrase ''and may not be changed or modified during the course of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician,'' because the requirements for modifying the compensation are codified in this final rule at § 411.354(d)(1)(ii).

Under § 411.354(d)(1)(i), compensation is deemed to be set in advance if the compensation is ''set out in writing before the furnishing of items or services'' and the other requirements of § 411.354(d)(1)(i) are met. In the proposed rule, we stated that, because the special rule on the set in advance requirement at § 411.354(d)(1) is an optional deeming provision and not a requirement, in order to satisfy the set in advance requirement included in various exceptions in § 411.357, it is not necessary that the parties reduce the compensation to writing before the furnishing of items or services. Given the writing requirement in the new rule at § 411.354(d)(1)(ii) on modifying compensation during the course of an arrangement, we are qualifying this statement in this final rule. As finalized in this rule, compensation may be set in advance even if it is not set out in writing before the furnishing of items or services as long as the compensation is not modified at any time during the period the parties seek to show the compensation was set in advance. For example, assume that the parties to an arrangement agree on the rate of compensation before the furnishing of items or services, but do not reduce the compensation rate to writing at that point in time. Assume further that the first payment under the arrangement is documented and that, under § 411.354(e)(4), during the 90-day period after the items or services are

initially furnished, the parties compile sufficient documentation of the arrangement to satisfy the writing requirement of an applicable exception. Finally, assume that the written documentation compiled during the 90-day period provides for a rate of compensation that is consistent with the documented amount of the first payment, that is, the rate of compensation was not modified during the 90-day period. Under these specific circumstances, we would consider the compensation to be set in advance. More broadly speaking, records of a consistent rate of payment over the course of an arrangement, from the first payment to the last, typically support the inference that the rate of compensation was set in advance. On the other hand, under § 411.354(d)(1)(ii), if the parties modify the compensation (or formula for determining the compensation) during the 90-day period (or thereafter), the modified compensation (or formula for determining the compensation) must be set out in writing before the furnishing of items or services for which the modified compensation is to be paid. To the extent that our preamble discussion in the CY 2016 PFS final rule suggested that the rate of compensation must always be set out in writing before the furnishing of items or services in order to meet the set in advance requirement of an applicable exception, we are retracting that statement (80 FR 71317).

We noted in the proposed rule and reiterate here that there are many ways in which the amount of or a formula for calculating the compensation under an arrangement may be documented before the furnishing of items or services (84 FR 55815). It is not necessary that the document stating the amount of or a formula for calculating the compensation, taken by itself, satisfies the writing requirement of the applicable exception; the document stating the amount of or a formula for calculating the compensation may be one document among many which, taken together, constitute a collection of documents sufficient to satisfy the writing requirement of the applicable exception as interpreted at § 411.354(e)(2). For example, depending on the facts and circumstances, informal communications via email or text, internal notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules, or other documents recording similar payments to or from other similarly situated physicians for similar items or services, may be sufficient to establish that the amount of or a formula for calculating the compensation was set in advance before the furnishing of items or services. Even if the amount of or a formula for calculating the compensation is not set in advance, depending on the facts and circumstances, the parties may be able to rely on the new exception for limited remuneration to a physician at § 411.357(z). Under § 411.357(z), if an entity initially pays a physician for services utilizing the exception for limited remuneration to a physician and the parties subsequently decide to continue the arrangement utilizing an exception that requires the compensation to be set in advance, such as the exception for personal service arrangements at § 411.357(d)(1), depending on the facts and circumstances, the parties may be able to use documentation of the initial payments made while utilizing § 411.357(z) to establish that the amount of or a formula for calculating the compensation was set in advance before the furnishing of services under the subsequent personal service arrangement.

In the proposed rule, we clarified our longstanding policy that an electronic signature that is legally valid under Federal or State law is sufficient to satisfy the signature requirement of various exceptions in our regulations and sought comments on whether we should codify this policy in our regulations. We also noted that the collection of writings that parties may rely on under § 411.354(e)(2) to satisfy the writing requirement of our exceptions may include documents and records that are stored electronically (84 FR 55815). In response to commenters, we are codifying a new special rule for electronic signatures at § 411.354(e)(3); the special rule on writing and signature requirements, which was proposed at § 411.354(e)(3), will be designated as § 411.354(e)(4). While we are not codifying our policy on electronic documents, we are reaffirming in this final rule our policy that the documents that may be used to satisfy the writing requirement under § 411.354(e)(2) include electronically stored documents.

After reviewing the comments, we are finalizing the special rule for writing and signature requirements without modification at § 411.354(e)(4). In addition, to clarify the set in advance requirement in various exceptions and to prevent program or patient abuse, we are finalizing requirements for modifying compensation (or the formula used to calculate compensation) during the course of an arrangement at § 411.354(d)(1)(ii); for modified compensation under an arrangement to be set in advance, it must satisfy these requirements. We are also finalizing a special rule for electronic signatures at § 411.354(e)(3), codifying our longstanding policy that an electronic signature that is valid under Federal or State law is sufficient to satisfy the signature requirement of various physician self-referral law exceptions.

We received the following comments and our responses follow.

Comment: We received nearly unanimous support for our proposal to allow parties up to 90 consecutive calendar days to satisfy the writing and signature requirements of various physician self-referral law exceptions. Commenters stated that the proposal, if finalized, would reduce administrative burden associated with the documentation requirements of the exceptions to the physician self-referral law, provide flexibility in situations where an arrangement begins before key terms and conditions are reduced to writing, and allow entities to avoid so-called technical noncompliance that may lead to disclosures of nonabusive arrangements to the SRDP.

Response: We agree with the commenters that the policy as finalized affords greater flexibility and will reduce the administrative burden associated with the writing and signature requirements. We believe that, with the clarification of the set in advance requirement detailed below, the special rule on writing and signature requirements at § 411.354(e)(4) will not pose a risk of program or patient abuse, and we are finalizing it as proposed.

Comment: Several commenters supported our proposal to allow parties additional time to obtain required writings and signatures, but encouraged us to adopt a 120- or 180-day period instead of the proposed 90-day period for obtaining required writings and signatures. According to some commenters, if, as required under the proposed special rule, a compensation arrangement complies with all the requirements of an applicable exception except for the writing and signature requirements, a 180-day grace period for compliance with the writing and signature requirements poses a low risk of program or patient abuse. One commenter stated that a grace period of 120 days is necessary for a large health care system to obtain required writings and signatures, given the large number of contracts the system must review and the time it takes for staff to review the contracts. Another commenter stated that small practices may need up to 120 days to comply with the writing and signature requirements.

Response: We decline to extend the special rule to allow parties up to 120 or 180 days to comply with the writing and signature requirements. With respect to the signature requirement, section 1877(h)(1)(E) of the Act currently provides for a period of 90 consecutive calendar days for parties to obtain missing signatures, and we are not persuaded that we could extend the period to 120 or 180 days under section 1877(b)(4) of the Act without posing a risk of program or patient abuse. Regarding the writing requirement, we believe that the requirement is important for ensuring transparency in potentially lucrative compensation arrangements, and we believe that extending the grace period to 120 or 180 days could pose a risk of program or patient abuse.

We believe that allowing a period of 90 consecutive calendar days to satisfy the writing and signature requirements sufficiently addresses legitimate concerns regarding the administrative burden of the writing and signature requirements and inadvertent ''technical'' noncompliance, especially in light of the clarification of the writing requirement at § 411.354(e)(2) and the new exception for limited remuneration to a physician at § 411.357(z), which may be used to protect an arrangement at its inception while parties collect required documentation and signatures to satisfy the writing and signature requirements of other exceptions on a going-forward basis.

Commenter: One commenter objected on both legal and policy grounds (the policy objections are discussed in the next comment and response) to the proposal to allow parties up to 90 consecutive calendar days to document arrangements in writing, especially for personal service arrangements excepted under § 411.357(d). The commenter stated that CMS lacks the legal authority to permit parties up to 90 consecutive calendar days to document an arrangement in writing. The commenter maintained that the codification of the 90-day signature rule in the BiBA expressly provides that, except for the signature requirement, an arrangement must comply with all the other requirements of an exception, including the writing requirement. The commenter concluded that the Congress did not intend that the 90-day signature rule to be expanded to include the writing requirement.

Response: Our proposal to allow parties up to 90 consecutive calendar days to document arrangements in writing does not waive the writing requirement in various statutory and regulatory exceptions, including the exception for personal service arrangements at § 411.357(d). Rather, our proposal was made pursuant to section 1877(h)(1)(D) of the Act, which expressly grants the Secretary the authority to determine the means by which the writing requirement in various exceptions is satisfied. In this context, the special rule we are finalizing at § 411.354(e)(4) functions as a deeming provision. As long as parties obtain the required writings and signatures within 90 consecutive calendar days (and the other requirements of an applicable exception are met), the arrangement is *deemed* to have met the writing and signature requirement, including for the first 90 days of the arrangement. Thus, with respect to the statutory special rule for signature requirements at section 1877(h)(1)(E) of the Act, if the parties obtain the required writing within 90 consecutive calendar days and the arrangement satisfies all the other requirements of an applicable exception, then the arrangement ''otherwise complies with all criteria of the applicable exception'' for the initial 90-day period, including the writing requirement. While it is true that the Congress did not explicitly extend the 90-day period for signature requirements in section 1877(h)(1)(E) of the Act to the writing requirement in various exceptions, we do not believe that section 1877(h)(1)(E) of the Act limits the grant of authority in section 1877(h)(1)(D) of the Act to determine the means by which the writing requirement may be satisfied.

We note that, in addition to the authority granted to the Secretary under section 1877(h)(1)(D) of the Act, the Secretary has authority under section 1877(b)(4) of the Act to issue regulations excepting financial relationships that do not pose a risk of program or patient abuse. In the FY 2009 IPPS final rule, we explained that, although the Secretary cannot grant immunity for violations or waive requirements of the physician self-referral law, the Secretary is authorized under section 1877(b)(4) of the Act to propose alternative methods for compliance with the physician self-referral law, including amendments to our regulations that keep within the exceptions certain financial relationships that would otherwise be out of compliance with the physician self-referral law (73 FR 48707 through 48709). Relying on this authority, in the FY 2009 IPPS final rule, we finalized the special rule for temporary noncompliance with signature requirements at § 411.353(g) (73 FR 48702 through 48703), which the Congress in the BiBA codified in the substantively identical special rule for signature requirements at section 1877(h)(1)(E) of the Act. As with the special rule for temporary noncompliance with signature requirements finalized in the FY 2009 IPPS final rule, the Secretary has the authority under section 1877(b)(4) of the Act to propose alternative methods for compliance with the writing requirement of various physician self-referral law exceptions, if the financial relationships ultimately protected under the exceptions do not pose a risk of program or patient abuse. Based on our administration of the SRDP and our experience working with our law enforcement partners, we conclude that an arrangement that satisfies all the requirements of an applicable exception for the duration of the arrangement, including the set in advance requirement as detailed below, but is not initially set out in writing or signed (or both) for a period of no longer than 90 consecutive calendar days, does not pose a risk of program or patient abuse. Therefore, the Secretary also has authority under section 1877(b)(4) of the Act to issue the new special rule for writing and signature requirements at § 411.357(e)(4).

Comment: In addition to the objection discussed above, one commenter objected strongly to the proposed policy to permit parties up to 90 consecutive calendar days to document personal service arrangements. According to the commenter, the proposal, if finalized, would allow parties to routinely, intentionally, and repeatedly enter into oral agreements worth thousands of dollars, without sufficient transparency to determine if the arrangements comply with all the other requirements of an exception. Specifically, the commenter expressed concern that parties would use the ''grace period'' to adjust compensation upward or downward based on a physician's referrals, and these adjustments would be virtually impossible to detect, because the original arrangement would not be documented. The commenter doubted whether parties that do not timely document arrangements at their inception would assiduously comply with all the other requirements of an exception.

Response: We believe that the set in advance requirement, as clarified and codified in this final rule, addresses the commenter's concern that parties will adjust the compensation under an arrangement upward or downward during the first 90 days of the arrangement in a manner that takes into account the volume or value of referrals

or other business generated by the physician, and that these adjustments will be virtually impossible to detect. In the proposed rule, we emphasized that, other than the writing and signature requirements, the special rule on writing and signature requirements requires an arrangement to satisfy *all* the requirements of an applicable exception, including the set in advance requirement, for the entire term of the arrangement, including the first 90 days (84 FR 55814). Under the current special rule for compensation that is considered set in advance at § 411.354(d)(1) (that is, the special rule in effect prior to the effective date of this final rule), the formula for determining compensation cannot be changed or modified during the course of an arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Thus, to the extent that compensation is adjusted upwards or downwards during the first 90 days of an arrangement in a manner that takes into account the volume or value of referrals or other business generated, as described by the commenter, the compensation would not be considered to be set in advance under current § 411.354(d)(1). However, as we explained in the proposed rule, the special rule at current § 411.354(d)(1) is merely a deeming provision, not a requirement (84 FR 55814).

We share the commenter's concern regarding inappropriate and potentially undetectable changes in compensation during the first 90 days of an arrangement and thereafter. Although modifications of the compensation terms of an arrangement are permissible under the physician self-referral law (*see* 73 FR 48697), such modifications may pose a risk of program or patient abuse, because the modifications could be made—either retroactively or prospectively—in a manner that takes into account the volume or value of a physician's referrals or other business generated by the physician. We believe that, in order to prevent program or patient abuse, including abuse of the 90-day ''grace period'' for documenting an arrangement in writing under final § 411.354(e)(4), it is necessary to codify in our regulations certain *requirements,* including a writing requirement, for modified compensation to meet the set in advance requirement of various exceptions. Unlike the deeming provision in current § 411.354(d)(1), which will be redesignated as § 411.354(d)(1)(i), compliance with the new set in advance rule at § 411.354(d)(1)(ii) will be *required* for any modification of the compensation terms of an arrangement. The set in advance requirements at § 411.354(d)(1)(ii) are based on preamble guidance in the FY 2009 IPPS final rule on the requirements for amending compensation arrangements (73 FR 48696 through 48697).

Under final § 411.354(d)(1)(ii), compensation (or a formula for determining the compensation) that is modified at any time during the course of a compensation arrangement, including the first 90 days of the arrangement, satisfies the set in advance requirement of various exceptions only if all of the following conditions are met: (1) All requirements of an applicable exception in §§ 411.355 through 411.357 are met on the effective date of the modified compensation (or the formula for determining the modified compensation); (2) the modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid; and (3) before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified. Importantly, parties will *not* have 90 days under § 411.354(d)(1)(ii) to reduce the modified compensation (or the formula for determining the modified compensation) to writing. Rather, the modified compensation (or the formula for determining the modified compensation) must be set forth in writing in sufficient detail so that it can be objectively verified *before* the furnishing of items, services, office space, or equipment for which the modified compensation is to be paid. Given our program integrity concerns, as well as the concerns identified by the commenter with modifications to the compensation terms of an arrangement, we believe that the transparency afforded by a writing requirement is necessary for modifying compensation, including modifying compensation during the first 90 days of an arrangement.

Under § 411.354(d)(1)(ii)(A), the amended arrangement, including the modified rate of compensation, must satisfy the requirements of an applicable exception anew. For example, suppose that an arrangement for call coverage at the rate of $500 per 24-hour shift of coverage satisfies all the requirements of the exception for personal service arrangements at § 411.357(d)(1) on day 1. If, on day 70, the parties agree to modify the compensation to $600 per 24-hour shift, the arrangement *as amended* must satisfy all the requirements of the exception for personal service arrangements; thus, the compensation under the amended arrangement (that is, $600 per 24-hour shift) may not exceed fair market value for the call coverage and may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician, and the other requirements of the exception for personal service arrangements must also be satisfied. In addition, as required by § 411.354(d)(1)(ii)(B), the amended compensation rate may not be retroactive (that is, the physician may not be paid at the rate of $600 per 24-hour shift for services provided from day 1 to day 69). Lastly, under § 411.354(d)(1)(ii)(C), the modified compensation (or formula for determining the compensation) must be set forth sufficiently in writing *before* the furnishing of the services for which the modified compensation is to be paid. Thus, if the physician provides the first shift of call coverage at the rate of $600 per 24-hour shift on day 75, the modified rate of compensation must be set forth in writing in sufficient detail so that it can be objectively verified before the services are furnished on day 75. Under § 411.354(e)(4), the parties will still have through day 90 to reduce the entire arrangement to writing and to obtain required signatures, but in order for the modified compensation (or formula for determining the compensation) to satisfy the set in advance requirement, it must be in writing before the furnishing of services on day 75. If the parties again modify the compensation terms of the arrangement effective, for example, on day 180, all the conditions for modifying the compensation under § 411.354(d)(1)(ii) must be met again, and the modified compensation must be sufficiently set forth in writing before the furnishing of services on day 180. (There is no signature requirement under § 411.354(d)(1)(ii), so the writing that documents the modified compensation need not be signed by the parties.)

As noted in Phase III, in certain instances, modifications to an arrangement may be material to the compensation terms of the arrangement, without directly modifying the amount of compensation under an arrangement (72 FR 51044). Returning to the example above, assume the parties modified the arrangement on day 70 to reduce the

call coverage shift from 24 to 12 hours, but retained the compensation amount of $500 per shift. For purposes of the physician self-referral law, the modification is material to the compensation terms of the arrangement because it raises questions as to whether the compensation under the amended arrangement ($500 per 12-hour shift) satisfies requirements pertaining to fair market value and the volume or value of referrals or other business generated. It is our view that such an amendment is a modification of the formula for determining compensation ($500 per 12-hour shift versus $500 per 24-hour shift), and this modification must meet all conditions of § 411.354(d)(1)(ii) in order to avoid the physician self-referral law's referral and billing prohibitions. On the other hand, modifications that do not affect the compensation terms of the arrangement need not meet the conditions of § 411.354(d)(1)(ii); for example, if the parties amend the schedule for the provision of call coverage from Tuesdays to Thursdays but there are no other changes to their arrangement, § 411.354(d)(1)(ii) would not be triggered. Lastly, reflecting our current policy, § 411.354(d)(1)(ii) does not require that the modified compensation remain in place for at least 1 year from the date of amendment and there is no prohibition on the number of times the parties may modify the compensation, provided that the conditions of § 411.354(d)(1)(ii) are met each time the compensation is modified. We caution against a practice of frequently or repeatedly modifying the compensation terms over the course of an arrangement and remind readers that, under § 411.354(d)(1)(ii), each time the compensation is modified, the parties must establish anew that the arrangement—as modified—satisfies all the requirements of an applicable exception.

Given our clarification and codification at § 411.354(d)(1)(ii) of the conditions that modified compensation must meet in order to be set in advance, we believe that our interpretation of writing and signature requirements as set forth at § 411.354(e)(4) does not pose a risk of program or patient abuse. To reiterate, with the exception of the writing and signature requirements, a compensation arrangement must satisfy all the requirements of an applicable exception, including the set in advance requirement, during the initial 90 days of the arrangement (and thereafter). Any modification of the compensation terms of an arrangement during the initial 90 days (or thereafter) must meet all the conditions of § 411.354(d)(1)(ii) in order for the compensation to be set in advance. If parties modify the compensation terms of an arrangement during the first 90 days (or thereafter), the modified compensation arrangement will have to satisfy all the requirements of an applicable exception, including applicable requirements pertaining to fair market value and the volume or value of referrals or other business generated by the referring physician. In addition, under § 411.354(d)(1)(ii)(C), the modified compensation (or formula for determining the compensation) must be sufficiently set forth in writing *before* the furnishing of items, services, office space, or equipment for which the modified compensation is to be paid, even if the modification occurs during the first 90 days of the arrangement. Thus, notwithstanding the 90-day period for obtaining required writings and signatures under § 411.354(e)(4), parties will not be permitted to modify the compensation terms of an arrangement during the first 90 days without documenting the modification in writing, and modifications to the compensation (or formula for determining the compensation) may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

Lastly, the commenter doubted that parties that fail to document their arrangements during the first 90 days of the arrangement work diligently to ensure compliance with other requirements of applicable exceptions. Our experience administering the SRDP suggests otherwise. We have reviewed a large number of arrangements that satisfied all the requirements of an applicable exception except the writing and signature requirements. We have learned that parties neglect to document arrangements in writing and sign the writings for a variety of reasons, such as administrative oversight or personnel changes. At the same time, we continue to believe that the writing requirement functions as an important safeguard to provide transparency and prevent program or patient abuse, and we reiterate that the best practice is to document compensation arrangements in writing from the outset. We believe that § 411.354(e)(4) provides sufficient flexibility for nonabusive arrangements that fully satisfy all the requirements of an exception other than the writing or signature requirement, while incenting parties to act diligently to sign and document arrangements within 90 consecutive calendar days of the commencement of their arrangement. We also stress that arrangements that fail to satisfy all the requirements of an applicable exception other than the writing and signature requirement during the first 90 days (and thereafter) would not be protected under § 411.354(e)(4).

Comment: Several commenters appreciated CMS' statement that the set in advance requirement does not require parties to set out the compensation in writing in advance of the furnishing of items or services, and that the special rule on the set in advance requirement at § 411.354(d)(1) is a deeming provision, not a requirement. One commenter noted that the clarification would greatly benefit hospitals that inadvertently fail to document their compensation terms prior to starting performance. Another commenter found helpful our preamble guidance regarding the set in advance requirement and the use of practice patterns, including consistent payments patterns, to establish that the rate of compensation was set in advance. The commenter stated that a grace period of more than 90 days may be necessary in some circumstances to establish an identifiable pattern of payments.

Response: As explained above, under § 411.354(e)(4), other than the writing and signature requirements, a compensation arrangement must satisfy all the requirements of an applicable exception, including the set in advance requirement, for the entire duration of the arrangement, including the first 90 days of the arrangement. Thus, the compensation (or formula for calculating the compensation) must be determined before the furnishing of items or services for which compensation is to be paid. A party submitting a claim for payment for a designated health service retains the burden of proof under § 411.353(c)(2) to establish that all the requirements of an applicable exception, including the set in advance requirement, if applicable, are met. The surest and most straightforward way for a party to establish that the compensation under an arrangement is set in advance is to satisfy the deeming provision at § 411.354(d)(1)(i). Under § 411.354(d)(1)(i), parties that document the compensation in writing prior to the furnishing of items, services, office space, or equipment in sufficient detail so that it can be verified are *deemed* to satisfy the set in advance requirement. However, we are reiterating in this final rule that the compensation (or the formula determining the compensation) does not need to be documented in writing and it does not need to be deemed to be set in advance under § 411.354(d)(1)(i) in order to satisfy the

set in advance requirement during the first 90 days of the arrangement.

In order for an arrangement to meet the writing requirement of an applicable exception on an ongoing basis, the compensation (or formula for calculating compensation) must be documented in writing by the time the 90-day period under § 411.354(e)(4) expires. As we explained in the CY 2016 PFS, to determine compliance with the writing requirement, the relevant inquiry is whether the available contemporaneous documents (that is, documents that are contemporaneous with the arrangement) would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made (80 FR 71315). A reasonable person could not verify whether the compensation under an arrangement complies with an applicable fair market value requirement, for example, if the person could not determine from the documentation what the compensation was under the arrangement. Thus, by day 91, the compensation terms of the arrangement must be documented in writing in order to satisfy the writing requirement of an applicable exception. As explained above, we decline to extend the ''grace period'' for collecting required writings beyond the 90-day period. We believe that 90 consecutive calendar days provides sufficient time to document an arrangement to show compliance with the requirements of an applicable exception, including the set in advance requirement.

Comment: One commenter requested additional guidance from CMS on the interim systems and documents that may be relied upon to satisfy the requirement that rental rates are set in advance during the 90-day grace period. Specifically, the commenter asked whether a scheduling platform that tracks leasing arrangements and allocates leased square footage, scheduling actual space utilization and rent, would be sufficient to satisfy the set in advance requirement.

Response: The determination as to what constitutes sufficient documentation to establish that compensation under the arrangement is set in advance depends on the facts and circumstances in each case. Therefore, we cannot opine on whether the scheduling platform described by the commenter would be sufficient to establish that the set in advance requirement was met. We discussed in the proposed rule (and repeated above) the various documents that, depending on the facts and circumstances, may be used to establish that compensation is set in advance. We are clarifying the types of documents that, individually or taken together and depending on the facts and circumstances, may establish that compensation is set in advance. These documents include informal communications via email or text, internal notes to file, similar payments between the same parties for similar items or services under prior arrangements, generally applicable fee schedules, or, where no formal generally applicable fee schedule exists, other documents showing a pattern of payments to or from other similarly situated physicians for the same or similar items or services. This list is illustrative only and is not exhaustive. To avoid being overly prescriptive, we are not providing more determinant rules for establishing that compensation is set in advance.

Comment: Several commenters stated that, even if the proposed special rule is finalized, there would be continuing uncertainty regarding how parties can establish that compensation is set in advance if there is no signed writing and no steady, consistent stream of payments. Commenters noted that informal writings between the parties may not be detailed enough to satisfy the set in advance requirement and that, in certain instances, the compensation may only have been determined through in-person conversations, with no paper trail. The commenters also noted that fee schedules and comparisons to other arrangements may not be useful for compensation arrangements where the payment methodology is more complicated or customized to the specific financial relationship. Given these difficulties, the commenters requested that compensation be deemed to comply with all the requirements of an applicable exception, except the writing and signature requirements, if the parties certify in the signed writing documenting the arrangement that the arrangement met all the elements of the exception as of the commencement date of the arrangement. The commenters noted that this requirement would provide an additional safeguard, because a false certification could expose a person to potential liability under the False Claims Act, because it would be useful evidence of scienter.

A second group of commenters suggested that, to provide additional flexibility, CMS should create another special rule on the set in advance requirement at § 411.354(d). Under the commenters' proposal, compensation would be considered set in advance if: (1) The parties agree in advance that compensation under the arrangement will be fair market value and not determined in any manner that takes into account the volume or value of the physician's referrals prior to the commencement of the arrangement; (2) the parties work with reasonable diligence to establish the specific compensation amount or methodology; (3) the parties, in fact, establish the specific compensation amount or methodology within 90 days of the commencement of the arrangement; and (4) the resulting compensation is fair market value and commercially reasonable without taking into account the volume or value of referrals or other business generated by the physician. The commenters asserted that, as long as the compensation is ultimately fair market value and the arrangement is commercially reasonable, then there is no risk of program or patient abuse. The commenters further asserted that their proposal would be helpful for practices located in States that prohibit the corporate practice of medicine, because providers in those States cannot rely on the exception for *bona fide* employment relationships, which does not include a set in advance requirement. One commenter stressed that the special rule is especially needed if CMS finalizes its proposed definition of ''isolated financial transaction,'' as parties may have relied on this exception in the past to compensate physicians for services furnished prior to the parties setting the compensation under the arrangement.

Response: We decline to adopt the deeming provision suggested by the first commenters and the new special rule recommended by the second commenters. The set in advance requirement is a statutory requirement and, in our view, both proposals are inconsistent with the statutory requirement that the compensation is set *in advance.* In addition, as explained above, the set in advance requirement is an important safeguard to prevent program or patient abuse, including abuse of the 90-day grace period under § 411.354(e)(4). We believe that both proposals would be subject to the kinds of abuses described by the commenter above, namely undocumented and potentially undetectable adjustments of the compensation during the first 90 days of the arrangement that take into account the volume or value of referrals or other business generated by the physician. Even with a requirement that compensation is, in fact, fair market value, we believe that the proposals could be subject to abuse. Typically, fair market value is a range of values, and parties could use the 90-day period to adjust compensation upwards or downwards within this range. Therefore, we do not believe that we

have the authority under section 1877(b)(4) of the Act to waive the set in advance requirement for 90 days. In addition, although the Secretary has authority under section 1877(h)(1)(D) of the Act to determine how the writing requirement of various exceptions may be satisfied, we do not believe that this authority does not extend to the set in advance requirement.

With respect to the first commenters' proposal, parties documenting an arrangement after it has begun, as is permitted under § 411.354(e)(4), may choose to include memoranda or other notes describing earlier agreements, including verbal agreements or agreements made by informal communications that set the compensation (or formula for determining the compensation) in advance. The memoranda would not be sufficient for the compensation to be deemed to be set in advance under § 411.354(d)(1)(i), but, depending on the facts and circumstances, the memoranda could be used as evidence to help establish that the compensation was set in advance. We emphasize that there is no requirement under the physician self-referral law that parties create or retain such memoranda. As illustrated by our earlier discussion in this section II.D.5., there are a variety of ways to establish that compensation is set in advance, and, other than the deeming provision in § 411.354(d)(1)(i), we are not prescribing or recommending any particular approach.

With respect to the second commenters' proposed special rule, we note that the new rule for modifying compensation at § 411.354(d)(1)(ii) provides stakeholders certainty regarding the requirements that must be met in order for modified compensation to satisfy the set in advance requirement. Parties to an arrangement are permitted to enter into an arrangement that satisfies all the requirements of an applicable exception, including the set in advance requirement, and later modify the compensation terms of the arrangement, provided that the modified compensation is not retroactive and all the other conditions of § 411.354(d)(1)(ii) are met. This policy, coupled with the new exception for limited remuneration to a physician at § 411.357(z), which does not require compensation to be set in advance, should provide sufficient flexibility for all providers, including providers located in States that prohibit the corporate practice of medicine.

Comment: Some commenters stated that, if finalized, the proposed 90-day grace period and the clarification of the set in advance requirement, coupled with the newly proposed exception for limited remuneration to a physician, which does not require the compensation to be set in advance, would accommodate situations where a physician's services are needed on an urgent basis, and the compensation arrangement commences before the parties can set the compensation in advance or document the compensation.

Response: We agree with the commenters that, depending on the facts and circumstances, parties that do not have an opportunity to set compensation in advance may utilize the exception for limited remuneration to a physician at § 411.357(z) to protect an arrangement at its outset. If the parties decide to continue the arrangement on an ongoing basis, the parties may utilize another applicable exception without an annual limit, such as the exception for fair market value compensation at § 411.357(l). Depending on the facts and circumstances, records of payments made while utilizing the exception at § 411.357(z) may establish that the compensation under the ongoing arrangement satisfied the set in advance requirement of § 411.357(l). Parties that utilize the exception at § 411.357(l) (or another exception that requires the arrangement to be in writing and signed by the parties) for the ongoing arrangement have 90 consecutive calendar days to satisfy the writing and signature requirements under § 411.354(e)(4) once the parties begin to utilize that exception (or another applicable exception that requires the arrangement to be in writing and signed by the parties).

Comment; Several commenters urged us to finalize regulatory text, clearly stating CMS' policy that electronic signatures that are legally valid under Federal or State law are sufficient to satisfy the signature requirement of various exceptions. Some commenters also specifically asked that the regulatory text clarify that assent transmitted by email may satisfy the signature requirement. Other commenters recognized that CMS has declined in the past to specify what qualifies as a signature for purposes of the physician self-referral law, because CMS does not wish to be overly prescriptive. Nevertheless, the commenters requested that we explicitly confirm that a signature includes a sender's typed or printed name on an email or letterhead stationary that is one of the contemporaneous writings documenting an arrangement under § 411.354(e)(2).

Response: Our longstanding policy is that an electronic signature that is valid under applicable Federal or State law is sufficient to satisfy the signature requirement in various physician self-referral law exceptions. To provide greater clarity and certainty to stakeholders, we are codifying this policy at § 411.354(e)(3). We believe that what constitutes a valid signature that is sufficient to satisfy the signature requirement of various exceptions to the physician self-referral law depends on the facts and circumstances. We decline to provide a general rule regarding whether a sender's typed or printed name on an email or letterhead stationary would satisfy the requirement that an arrangement is signed by the parties. However, we note that, if an individual's typed or printed name on an email sent by that individual constitutes an electronic signature for purposes of applicable Federal or State law, then it qualifies as a ''signature'' for purposes of the physician self-referral law. Similarly, if the individual whose name is printed on the letterhead of the document being relied upon to satisfy the signature requirement of an applicable exception is also the sender of the document and the document would be considered signed by the individual under applicable Federal or State law, then it qualifies as a ''signature'' for purposes of the physician self-referral law. While a hand-written ''wet'' signature is the paradigmatic example of a signature, there is no requirement under the physician self-referral law that parties sign a document by hand, nor is there a requirement that electronic signatures be scanned copies of hand-written signatures. Any electronic signature that is valid under applicable Federal or State law is sufficient to satisfy the signature requirement under the physician self-referral law.

6. Exceptions for Rental of Office Space and Rental of Equipment (§ 411.357(a) and (b))

Section 1877(e)(1) of the Act establishes an exception to the physician self-referral law's referral and billing prohibitions for certain arrangements involving the rental of office space or equipment. Among other things, sections 1877(e)(1)(A)(ii) and (e)(1)(B)(ii) of the Act require the office space or equipment to be used exclusively by the lessee when being used by the lessee. The exclusive use requirements are incorporated into our regulations at § 411.357(a)(3) and (b)(2).

In the 1998 proposed rule, we stated our belief that the exclusive use requirement in the statute was meant to

prevent ''paper leases,'' where payment passes from a lessee to a lessor, even though the lessee is not actually using the office space or equipment (63 FR 1714). In Phase II, we further explained our interpretation of the exclusive use requirement (69 FR 16086). We stated that, after reviewing the statutory scheme, we believe that the purpose of the exclusive use requirement is to ensure that the rented office space or equipment cannot be shared with the lessor when it is being used or rented by the lessee (or any subsequent sublessee). In other words, a lessee (or sublessee) cannot ''rent'' office space or equipment that the lessor will be using concurrently with, or in lieu of, the lessee (or sublessee). We added that we were concerned that unscrupulous physicians or physician groups might attempt to skirt the exclusive use requirement by establishing holding companies to act as lessors. To foreclose this possibility, we modified the exclusive use requirements at § 411.357(a)(3) and (b)(2), to stipulate that the rented office space or equipment may not be ''shared with or used by the lessor or any person or entity related to the lessor'' when the lessee is using the office space or equipment. Disclosures to the SRDP have included several arrangements where multiple lessees use the same rented office space or equipment either contemporaneously or in close succession to one another, while the lessor is excluded from using the premises or equipment. At least one entity disclosed that it had invited a physician who was not the lessor into its office space to treat a mutual patient for the patient's convenience. The disclosing parties assumed that the arrangements violated the physician self-referral law, because, based on their understanding of the exceptions at § 411.357(a) and (b), the arrangements did not satisfy the exclusive use requirement of the applicable exception. As noted in the 1998 proposed rule and in Phase II, the purpose of the exclusive use rule is to prevent sham leases where a lessor ''rents'' space or equipment to a lessee, but continues to use the space or equipment during the period ostensibly reserved for the lessee. We do not interpret sections 1877(e)(1)(A)(ii) and (B)(ii) of the Act to prevent multiple lessees from using the rented space or equipment at the same time, so long as the lessor is excluded, nor do we interpret sections 1877(e)(1)(A)(ii) and (B)(ii) of the Act to prohibit a lessee from inviting a party other than the lessor (or any person or entity related to the lessor) to use the office space or equipment rented by the lessee. Moreover, we do not believe it would pose a risk of program or patient abuse for multiple lessees (and their invitees) to use the space or equipment to the exclusion of the lessor, provided that the arrangements satisfy all the requirements of the applicable exception for the rental of office space or equipment, and any financial relationships between the lessees (or their invitees) that implicate the physician self-referral law likewise satisfy the requirements of an applicable exception. Therefore, relying on the Secretary's authority under section 1877(b)(4) of the Act, we proposed to clarify our longstanding policy that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the space or equipment under § 411.357(a)(3) and 411.357(b)(2). Specifically, we proposed to add the following clarification to the regulation text: For purposes of this exception, exclusive use means that the lessee (and any other lessees of the same office space or equipment) uses the office space or equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space or the equipment.

After reviewing the comments, we are finalizing the proposal without modification.

We received the following comments and our responses follows.

Comment: Several commenters supported our clarification of the exclusive use requirement in § 411.357(a)(3) and (b)(2) as proposed. Commenters explained that as physician practices evolve to meet the rising costs of health care, the uncertainty regarding ''exclusive use'' is challenging when multiple physicians use the same space or equipment, a practice which the commenter stated is common; for example, a physician may invite a guest physician into the premises in order to coordinate and jointly treat a mutual patient. Commenters stated it would not pose a risk of program or patient abuse to allow multiple parties to use space or equipment concurrently.

Response: We agree with the commenters that the clarification of the exclusive use requirement in the exception for the rental of office space at § 411.357(a)(3) and the exception for the rental of equipment at § 411.357(b)(2) offers flexibility and certainty to providers, and that it does not pose a risk of program or patient abuse to permit multiple lessees (and their invitees) to use space or equipment concurrently, provided that all the other requirements of the exception are satisfied and that the lessor (or any person or entity related to the lessor) is excluded. We remind readers that the exceptions for the rental of office space and equipment both require, among other things, that the rental charges are consistent with fair market value, that the space or equipment that is rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement, and that the lease arrangement would be commercially reasonable even if no referrals were made between the lessee and lessor. If a lessor collects rental payments from multiple lessees for concurrent use of office space or equipment, these requirements and all the other requirements of § 411.357(a) or (b) must still be satisfied.

Comment: Multiple commenters requested that CMS update the new proposed language to permit lessors to use their own space or equipment along with lessees, especially when the lease provides access to space or equipment on a part-time basis. One commenter further explained that lessors should have the opportunity to utilize or lease such space to other lessees when it is not utilized as long as the leasing arrangements are properly administered and that any allocations of space, costs, or flow of funds can be audited, monitored and otherwise objectively verified to ensure accountability. Another commenter stated that, if a hospital leases space to a physician practice, the practice should be permitted to sublease back an exam room to the hospital for use by a hospital-employed physician or technician, in order to coordinate care. The commenter stated that if CMS is concerned about the risk of abuse, CMS could provide that space subleased back to the lessor must be at the same rate that the lessor leases the space to the tenant.

Response: Both the statute and our regulations require that leased office space or equipment is used exclusively by the lessee when it is being used by the lessee. We believe that the commenters' proposal would render this requirement meaningless. In addition, the exclusive use requirement is an important safeguard to prevent sham or ''paper'' leases, where a lessor collects rent from a lessee while continuing to use the leased office space or equipment during periods of time that are ostensibly reserved for the lessee. We also note that, under § 411.357(a)(3) and § 411.357(b)(2), rented office space or equipment may not exceed that which

is reasonable and necessary for the legitimate business purposes of the lease arrangement. We question if a lease arrangement satisfies this requirement if the lease includes space or equipment that is consistently not used by the lessee. For example, assume a physician owns a medical office building, a hospital leases the entire building from the physician, the hospital (sublessor) subleases an office suite to the physician (sublessee), and the remainder or a significant portion of the medical office building remains unused and unoccupied. On these facts, the amount of spaced leased by the hospital (that is, the entire medical office building) likely exceeds that which is reasonable and necessary for the legitimate business purposes of the lease arrangement.

We note that, as amended in this final rule, the exception for fair market value compensation at § 411.357(l) may be used for office space and equipment lease arrangements. The exception for fair market value does not include an exclusive use requirement. Rather, the exception includes as a substitute the requirement that the arrangement not violate the anti-kickback statute. Depending on the facts and circumstances, the arrangements described by the commenters may be permitted under the exception for fair market value compensation at § 411.357(l). We note, however, that the arrangements would have to satisfy the commercial reasonableness requirement at § 411.357(l)(4) and the remaining requirements of the exception for fair market value compensation.

7. Exception for Physician Recruitment (§ 411.357(e))

Section 1877(e)(5) of the Act established an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the hospital's medical staff. The exception at section 1877(e)(5) of the Act authorizes the Secretary to impose additional requirements on recruitment arrangements as needed to protect against program or patient abuse. The 1995 final rule incorporated the provisions of section 1877(e)(5) of the Act into our regulations at § 411.357(e). As finalized in the 1995 final rule, § 411.357(e) requires the recruitment arrangement to be in writing and signed by both parties, that is, the recruited physician and the hospital.

In Phase II, we substantially modified § 411.357(e). Relying on our authority under section 1877(b)(4) of the Act, we expanded the exception at § 411.357(e)(4) to address remuneration from a hospital (or a federally qualified health center (FQHC), which was added as a permissible recruiting entity under Phase II) to a physician who joins a physician practice. There, we established requirements for recruitment arrangements under which remuneration is provided by a hospital or FQHC indirectly to a physician through payments made to his or her physician practice as well as directly to the physician who joins a physician practice (69 FR 16094 through 16095). When payment is made to a physician indirectly through a physician practice that the recruited physician joins, the practice is permitted to retain actual costs incurred by the practice in recruiting the physician under § 411.357(e)(4)(ii), and, in the case of an income guarantee made by the hospital or FQHC to the recruited physician, the practice may also retain the actual additional incremental costs attributable to the recruited physician under § 411.357(e)(4)(iii). Under the Phase II regulation, if a recruited physician joined a physician practice, § 411.357(e)(4)(i) required the party to whom the payments are directly made (that is, the physician practice that the recruited physician joins) to sign the written recruitment agreement (69 FR 16139).

In Phase III, we responded to a commenter that requested clarification with respect to who must sign the writing documenting the physician recruitment arrangement (72 FR 51051). The commenter's concern was that § 411.357(e)(4)(i) could be interpreted to require that the recruiting entity (in the commenter's example, a hospital), the physician practice, and the recruited physician all had to sign one document. The commenter asserted that this would be unnecessary and would add to the transaction costs of the recruitment. The commenter suggested that we require a written agreement between the hospital and either the recruited physician or the physician practice to which the payments would be made or, in the alternative, that we should permit the hospital and the physician practice receiving the payments to sign a written recruitment agreement and require the recruited physician to sign a one-page acknowledgment agreeing to be bound by the terms and conditions set forth in that agreement. We responded that the exception for physician recruitment requires a writing that is signed by all parties, including the recruiting hospital (or FQHC or rural health clinic, which was added as a permissible recruiting entity under Phase III), the recruited physician, and the physician practice that the physician will be joining, if any, and explained that nothing in the regulations precluded execution of the agreement in counterparts.

We have reconsidered our position regarding the signature requirement at § 411.357(e)(4)(i). In the SRDP, we have seen arrangements in which a physician practice that hired a physician who was recruited by a hospital (or FQHC or rural health clinic) did not receive any financial benefit as a result of the hospital and physician's recruitment arrangement. Examples of such arrangements include arrangements under which: (1) The recruited physician joined a physician practice but the hospital paid the recruitment remuneration to the recruited physician directly; (2) remuneration was transferred from the hospital to the physician practice, but the practice passed all of the remuneration from the hospital to the recruited physician (that is, the practice served merely as an intermediary for the hospital's payments to the recruited physician and did not retain any actual costs for recruitment, actual additional incremental costs attributable to the recruited physician, or any other remuneration); and (3) the recruited physician joined the physician practice after the period of the income guarantee but before the physician's ''community service'' repayment obligation was completed. In each of the arrangements disclosed to the SRDP, the arrangement was determined by the disclosing party not to satisfy the requirements of the exception at § 411.357(e) solely because the physician practice that the recruited physician joined had not signed the writing evidencing the arrangement. We do not believe, however, that, under the circumstances described by parties disclosing to the SRDP, there exists a compensation arrangement between the physician practice and the hospital (or FQHC or rural health clinic) of the type against which the statute is intended to protect; that is, the type of financial self-interest that impacts a physician's medical decision making. Because the physician practice is not receiving a financial benefit from the recruitment arrangement, we do not believe it is necessary for the physician practice to also sign the writing documenting the recruitment arrangement between the recruited physician and the hospital (or FQHC or rural health clinic) in order to protect against program or patient abuse. We also believe that eliminating the signature requirement for a physician practice that receives no financial benefit under the recruitment

arrangement would reduce undue burden without posing a risk of program and patient abuse. For these reasons, we proposed to modify the signature requirement at § 411.357(e)(4)(i). We proposed to require the physician practice to sign the writing documenting the recruitment arrangement, if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

After reviewing the comments, we are finalizing the proposal without modification.

We received the following comment and our response follows.

Comment: Several commenters supported our proposal to modify the signature requirement at § 411.357(e)(4)(i) to require a physician practice to sign the writing documenting a recruitment arrangement between a physician and a hospital only if remuneration is provided to the physician indirectly through payments made to the physician practice and the physician practice does not pass directly through to the physician all the remuneration from the hospital. One commenter stated that eliminating the signature requirement for a physician practice would reduce burden without posing a risk of program and patient abuse.

Response: We agree with the commenters that the proposal will reduce the burden of compliance with the physician self-referral law without posing a risk of program or patient abuse. Therefore, we are finalizing the modification of the exception as proposed. We note in this context that a ''physician practice'' under § 411.357(e)(4) includes a sole practice consisting of only one physician. (*See,* for example, the definition of ''entity'' at § 411.351). Under the definition of ''physician'' at § 411.351, a physician and the professional corporation of which he or she is a sole owner are the same for purposes of the physician self-referral law. Thus, if a recruited physician joins an existing sole physician practice, and the recruited physician receives remuneration indirectly through payments made to the sole physician practice and the sole physician practice does not pass directly through to the recruited physician all the remuneration from the hospital, then the physician in the sole physician practice or someone authorized to sign on behalf of the physician's professional corporation must sign the writing documenting the arrangement.

8. Exception for Remuneration Unrelated to the Provision of Designated Health Services (§ 411.357(g))

Under section 1877(e)(4) of the Act, remuneration provided by a hospital to a physician does not create a compensation arrangement for purposes of the physician self-referral law, if the remuneration does not relate to the provision of designated health services. The statutory exception is codified in our regulations at § 411.357(g). Because our prior rulemaking regarding § 411.357(g) was based in part on an interpretation of legislative history, we reviewed the legislative history of section 1877(e)(4) of the Act and certain provisions that preceded it in the proposed rule.

As originally enacted by OBRA 1989, the referral and billing prohibitions of the physician self-referral law applied only to clinical laboratory services. OBRA 1989 created three general exceptions for both ownership and compensation arrangements at sections 1877(b)(1) through (3) of the Act, and granted the Secretary the authority at section 1877(b)(4) of the Act to create additional exceptions. Section 42017(e) of OBRA 1990 (Pub. L. 101–508) redesignated section 1877(b)(4) as 1877(b)(5) of the Act, and added an exception at section 1877(b)(4) of the Act for financial relationships with hospitals that are unrelated to the provision of clinical laboratory services. (To avoid confusion between the exception added by OBRA 1990 at section 1877(b)(4) of the Act and section 1877(b)(4) of the Act as it currently exists, the exception for financial relationships unrelated to the provision of clinical laboratory services enacted by OBRA 1990 is referred to herein as the ''OBRA 1990 exception.'') The OBRA 1990 exception applied to both ownership or investment interests and compensation arrangements, and excepted financial relationships between physicians (or immediate family members of physicians) and hospitals that did not relate to the provision of clinical laboratory services. OBRA 1993 eliminated the OBRA 1990 exception, but the Social Security Act Amendments of 1994 (Pub. L. 103–432) (SSA 1994) reinstated the exception through January 1, 1995.

In place of the OBRA 1990 exception, OBRA 1993 added a new exception at section 1877(e)(4) of the Act. Under section 1877(e)(4) of the Act, remuneration provided by a hospital to a physician that does not relate to the provision of designated health services is not considered a compensation arrangement for purposes of the referral and billing prohibitions. Although there are certain similarities between section 1877(e)(4) of the Act and the OBRA 1990 exception, the exception at section 1877(e)(4) of the Act is narrower than the OBRA 1990 exception in several important respects: (1) The OBRA 1990 exception excepts both ownership interests and compensation arrangements between hospitals and physicians, whereas section 1877(e)(4) of the Act applies only to compensation arrangements under which remuneration passes from the hospital to the physician; (2) the OBRA 1990 exception protects a broad range of financial relationships that are unrelated to the provision of clinical laboratory services, whereas section 1877(e)(4) of the Act has a narrower application, applying only to remuneration unrelated to the provision of designated health services; and (3) the OBRA 1990 exception applies to financial relationships between entities and physicians or their immediate family members, whereas section 1877(e)(4) of the Act applies only to compensation arrangements with physicians.

In the 1998 proposed rule, we proposed to revise our regulation at § 411.357(g) to reflect our interpretation of section 1877(e)(4) of the Act (63 FR 1702). (The prior regulation at § 411.357(g) was based on former sections 1877(b)(4) and (e)(4) of the Act as they were effective on January 1, 1992 (63 FR 1669).) We stated that, for remuneration from a hospital to a physician to be excepted under § 411.357(g), the remuneration must be ''completely unrelated'' to the furnishing of designated health services. We clarified that the remuneration could not in any direct or indirect way involve designated health services, and further that the exception would not apply in any situation involving remuneration that might have a nexus with the provision of, or referrals for, a designated health service (63 FR 1702). We further stated that the remuneration could in no way reflect the volume or value of a physician's referrals, and that payments to physicians that were ''inordinately high'' or above fair market value would be presumed to be related to the furnishing of designated health services. We provided the following examples of remuneration that might be completely unrelated to the furnishing of designated health services and excepted under § 411.357(g): (1) Fair market value rental payments made by a teaching hospital to a physician to rent his or her house in order to use the house as a residence for a visiting

faculty member; and (2) compensation for teaching, general utilization review, or administrative services.

In Phase II, we finalized the exception at § 411.357(g) with modifications (69 FR 16093 through 16094). As finalized, in addition to requiring that the remuneration does not in any way take into account the volume or value of the physician's referrals, § 411.357(g) requires that the remuneration is wholly unrelated (that is, neither directly nor indirectly related) to the furnishing of designated health services. The regulation stipulates that remuneration relates to the furnishing of designated health services if it: (1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles; (2) is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or (3) otherwise takes into account the volume or value of referrals or other business generated by the referring physician. We stated that we incorporated cost reporting principles in the regulation in order to provide the industry with bright-line rules to determine whether remuneration is related to the furnishing of designated health services (69 FR 16093). At the same time, we retracted the statement from the 1998 proposed rule that general utilization review or administrative services might not be related to the furnishing of designated health services. We justified our narrow interpretation of section 1877(e)(4) of the Act on the legislative history of the exception, noting that, initially, under the original statute, the exception was necessary to insulate a hospital's relationships with physicians that were unrelated to the provision of clinical laboratory services, a very small element of a hospital's practice. We continued that, since 1995, however, all hospital services are designated health services and a narrower interpretation of the exception is required to prevent abuse (69 FR 16093). We have made no changes to § 411.357(g) since Phase II. Commenters on Phase II stated that the Congress intended hospitals to be able to provide any amount of remuneration to physicians, provided that the remuneration did not *directly* relate to designated health services. In Phase III, based on our interpretation of the legislative history at that time, we reaffirmed our narrow interpretation of section 1877(e)(4) of the Act (72 FR 51056).

Based on our review of the statutory history of the OBRA 1990 exception and section 1877(e)(4) of the Act, and comments we received on our CMS RFI, we proposed certain modifications to the exception at § 411.357(g) to broaden the application of the exception. In the proposed rule, we stated that we continued to agree with the statement in Phase II that the exception at section 1877(e)(4) of the Act is significantly narrower than the OBRA 1990 exception. There are many financial relationships between hospitals and physicians that would be permissible under the OBRA 1990 exception because they do not relate, directly or indirectly, to the provision of clinical laboratory services. On the other hand, insofar as the exception at section 1877(e)(4) of the Act requires the remuneration to be unrelated to the provision of designated health services, and OBRA 1993 defines this term to include inpatient and outpatient services, the scope of protected compensation arrangements under section 1877(e)(4) of the Act is much narrower than that of the OBRA 1990 exception. Generally speaking, most financial relationships between hospitals and physicians relate to the furnishing of designated health services, in particular, inpatient or outpatient hospital services. That being said, we also considered in the proposed rule that OBRA 1993 did not merely strike the term ''clinical laboratory services'' in the OBRA 1990 exception and substituted the term ''designated health services.'' Rather, OBRA 1993 eliminated the OBRA 1990 exception and created a new (albeit somewhat similar) exception at section 1877(e)(4) of the Act. In light of this statutory history, in the proposed rule we stated that the most accurate interpretation of section 1877(e)(4) of the Act is not as a carryover of the 1990 OBRA exception into the significantly revised statutory regime established by OBRA 1993, but rather as a new exception that was intentionally created by the Congress in OBRA 1993, the very same legislation in which the Congress expanded the referral and billing prohibition of the physician self-referral law to inpatient and outpatient hospital services. We stated in the proposed rule that, in creating a new exception for remuneration unrelated to the provision of designated health services *and* expanding the definition of ''designated health services'' to include inpatient and outpatient hospital services, we believe that the Congress intended the exception to apply to a narrow—but not empty—subset of compensation arrangements between hospitals and physicians.

In the proposed rule, we reconsidered what remuneration, if any, is permissible under the exception if the exception does not apply to any item, cost, or service that could be allocated to Medicare or Medicaid under cost reporting principles, or to remuneration that is offered in any preferential or selective manner whatsoever based on comments received to the CMS RFI. We stated that we agreed with the commenters that the current exception is too restrictive and that the current § 411.357(g) has an extremely limited application (84 FR 55818).

To give appropriate meaning to the statutory exception at section 1877(e)(4) of the Act, we proposed to delete the current provisions at § 411.357(g)(1) and (2) in their entirety and to remove the phrase ''directly or indirectly'' from the regulation text. In place of existing § 411.357(g)(1) and (2), we proposed language that incorporates the concept of patient care services as the touchstone for determining when remuneration for an item or service is related to the provision of designated health services. In particular, we proposed regulation text to clarify that remuneration from a hospital to a physician does not relate to the provision of designated health services if the remuneration is for items or services that are not related to patient care services. We noted that section 1877(e)(4) of the Act specifically excepts remuneration unrelated to the *provision* of designated health services. For purposes of applying the exception at section § 411.357(g), we interpreted section 1877(e)(4) of the Act to except remuneration unrelated to the act or process of providing designated health services, a concept which is not as all-encompassing as remuneration that is unrelated in any manner whatsoever to designated health services. We stated our belief that patient care services provided by a physician, when the physician is acting in his or her capacity as a medical professional, are integrally related to the act or process of providing designated health services, regardless of whether such services are provided to patients of the hospital; thus, payment for such services relates to the provision of designated health services. Likewise, we proposed that items that are used in the act or process of furnishing patient care services are integrally related to the provision of designated health services, and payments for such items relate to the provision of designated health services. On the other hand, we also stated our belief that remuneration from a hospital to a physician for services that are not patient care services or

items that are not used in the act or process of providing designated health services does not relate to the *provision* of designated health services and would, therefore, not be prohibited under section 1877(e)(4) of the Act or our regulations at proposed § 411.357(g) (provided that the remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals).

In the proposed rule, we stated our belief that the concept of patient care services would provide a determinant and practicable principle for applying § 411.357(g) to compensation arrangements between hospitals and physicians. We also noted that the proposed regulation at § 411.357(g) retained the requirement that the remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals. Remuneration that is determined in any manner that takes into account the volume or value of a physician's referrals clearly relates to the provision of designated health services, regardless of the nature of the item or service for which the physician receives remuneration. Thus, the proposed provisions at § 411.357(g)(2) and (g)(3), which were intended to clarify when remuneration does not relate to the provision of designated health services, would not have applied to remuneration that is determined in any manner that takes into account the volume or value of a physician's referrals (84 FR 55816 through 55817).

In the proposed rule, we stated that remuneration from a hospital to a physician that pertains to the physician's patient care services is the paradigm of remuneration that relates to the provision of designated health services. Most obviously, when a physician provides patient care services to hospital patients, the physician's patient care services are directly correlated with the provision of designated health services. Thus, remuneration from the hospital to the physician for such services is clearly related to designated health services. However, we noted in the proposed rule that there does not have to be a direct one-to-one correlation between a physician's services and the provision of designated health services in order for payments for the service to be related to the provision of designated health services. For example, payment for emergency department call coverage relates to the furnishing of designated health services, even if the physician is not as a matter of fact called to the hospital to provide patient care services, because the hospital is paying the physician to be available to provide patient care services at the hospital. Similarly, medical director services typically include, among other things, establishing clinical pathways and overseeing the provision of designated health services in a hospital. Under our proposal, payments for such services would relate to the furnishing of designated health services for purposes of applying the exception at proposed § 411.357(g). We also stated that utilization review services are closely related to patient care services, and for this reason, we considered remuneration for such services to be related to the furnishing of designated health services (84 FR 55818).

In contrast to the services described above, in the proposed rule we stated that the administrative services of a physician pertaining solely to the business operations of a hospital are not related to patient care services. Thus, under our proposal, if a physician were a member of a governing board along with persons who were not licensed medical professionals, and the physician received stipends or meals that were available to the other board members, we would not have considered the remuneration provided to the physician to relate to the provision of designated health services, provided that the physician's compensation for the administrative services was not determined in a manner that takes into account the volume or value of his or her referrals. In this instance, we stated that the dispositive factor in determining that a physician's services are not related to the provision of designated health services is that the services are also provided by persons who are not licensed medical professionals, and the physician is compensated on the same terms and conditions as the non-medical professionals. Because the services could be provided by persons who are not licensed medical professionals, we concluded that the services were not patient care services. To provide clarity for stakeholders, we proposed a general principle at § 411.357(g)(3) for determining when remuneration for a particular service, when provided by a physician, is related to the provision of designated health services. We stated that, if a service can be provided legally by a person who is not a licensed medical professional *and* the service is of the type that is typically provided by such persons, then payment for such a service is unrelated to the provision of designated health services and may be protected under proposed § 411.357(g), provided that it is not determined in a manner that takes into account the volume or value of the physician's referrals. We noted in this context that ''licensed medical professional'' would include, but would not be limited to, a licensed physician. That is, if a service could be provided legally by both a physician and a medical professional who is not a physician, such as a registered nurse, but the service could not be provided by a person who is not a licensed medical professional, it would still be considered a patient care service under § 411.357(g)(3) as proposed. Thus, we proposed that remuneration provided by a hospital to a physician for the service would not be excepted under § 411.357(g), notwithstanding the fact that the service does not have to be performed by a *physician* (84 FR 55818 through 55819).

In the proposed rule, we stated that with respect to remuneration from a hospital for items provided by a physician, typical examples of remuneration that is related to the provision of designated health services include the rental of medical equipment and purchasing of medical devices from physicians. Because these items are used in the provision of patient care services, and patient care services may be designated health services or be directly correlated with the provision of designated health services, we concluded that remuneration for such items clearly relates to the provision of designated health services. We also stated that rental of office space where patient care services are provided, including patient care services that are not necessarily designated health services, is remuneration related to the provision of designated health services. In contrast, we stated that, if a physician who joins another practice sells the furniture from his or her medical office to a hospital, and the hospital places the furniture in the hospital's facilities, as long as the payment is not determined in a manner that takes into account the physician's referrals, the remuneration would not be considered to be related to the provision of designated health services under our proposal. Also, we stated our continued belief that, as first stated in the 1998 proposed rule, § 411.357(g) is available to except rental payments made by a teaching hospital to a physician to rent his or her house in order to use the house as a residence for a visiting faculty member. To provide stakeholders with greater clarity, we proposed to stipulate in regulation that remuneration provided in exchange for any item, supply, device, equipment, or office space that

is used in the diagnosis or treatment of patients, or any technology that is used to communicate with patients regarding patient care services, is presumed to be related to the provision of designated health services for purposes of § 411.357(g) (84 FR 55819).

In the proposed rule, we stated our belief that § 411.357(g)(2) and (3) would provide clarity regarding when payments for items and services relate to the provision of designated health services, and also give the meaning to the statutory exception. We stated that the requirement pertaining to the volume or value of a physician's referrals at § 411.357(g)(1) would ensure that payments to a physician for items or services that are ostensibly not related to patient care services are not in fact disguised payments for the physician's referrals. We sought comments on our proposals, as well as other possible ways for distinguishing between remuneration that is related to the provision of designated health services and remuneration that is unrelated to the provision of designated health services. Specifically, we sought comment as to whether we should limit what we consider to be ''remuneration related to the provision of designated health services'' to remuneration paid explicitly for a physician's provision of designated health services to a hospital's patients (84 FR 55819).

We received the following comment and our response follows.

Comment: Commenters on the proposal generally supported our efforts to restore utility to the statutory exception, but a few commenters expressed valid concerns that the expansion of the exception, especially without substantial guidance and examples of its application, would risk program or patient abuse. One commenter noted that ''patient care services'' is a defined term under our regulations, and it is not clear whether the term ''patient care services'' as used in § 411.357(g) was intended to have the same meaning as ''patient care services'' as defined at § 411.351. Many commenters, citing uncertainty in applying the proposed exception, requested codification of specific remuneration that would be deemed not to relate to the provision of designated health services.

Response: Given the concerns raised by commenters, we are not finalizing our proposed revision to § 411.357(g) at this time. We are continuing to evaluate the best way to restore utility to the statutory exception, and we may finalize revisions to the exception for remuneration unrelated to the provision of designated health services in future rulemaking.

9. Exception for Payments by a Physician (§ 411.357(i))

Section 1877(e)(8) of the Act excepts payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services, or to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value. The 1995 final rule (60 FR 41929) incorporated the provisions of section 1877(e)(8) of the Act into our regulations at § 411.357(i). In the 1998 proposed rule, we proposed to interpret ''other items and services'' to mean any kind of item or service that a physician might purchase (that is, not limited to ''services'' for purposes of the Medicare program in § 400.202 of this Chapter), but not including clinical laboratory services or those items or services that are specifically excepted by another provision in §§ 411.355 through 411.357 (63 FR 1703). We stated that we did not believe that the Congress meant the exception for payments by a physician to protect financial relationships that were covered by more specific exceptions with specific requirements, such as the exceptions for rental arrangements at section 1877(e)(1) of the Act.

In Phase II, we responded to commenters that disagreed with our position that the exception for payments by a physician is not available for arrangements involving any items or services excepted by another exception (69 FR 16099). We reiterated the statutory interpretation from the 1998 proposed rule, explaining that the determination that items and services addressed by another exception should not be covered in this exception is consistent with the overall statutory scheme and purpose and is necessary to prevent the exception for payments by a physician from negating the statute (69 FR 16099; *see also* 72 FR 51057). As a result, we made no changes to the regulation at § 411.357(i) in Phase II. Thus, as finalized in Phase II, the exception for payments by a physician at § 411.357(i) stated that the exception could not be used for items or services that are specifically *excepted* by another exception in §§ 411.355 through 411.357, with a parenthetical clarifying that this included the exception for fair market value compensation at § 411.357(l). However, at that time, the exception for fair market value compensation applied only to the provision of items or services *by* physicians *to* entities; the exception did not apply to items or services provided by entities to physicians.

Following the publication of Phase II, commenters complained that neither § 411.357(i) nor § 411.357(l) were available to protect many arrangements wherein physicians purchased items and services from entities, because: (1) The exception for payments by a physician was limited to the purchase of items and services not specifically excepted by another exception in §§ 411.355 through 411.357 (including § 411.357(l)); and (2) the exception for fair market value compensation did not apply to items or services provided by an entity to a physician (72 FR 51057). In response to the commenters, we expanded § 411.357(l) in Phase III to include both items and services furnished by physicians to entities *and* items and services furnished by entities to physicians (72 FR 51094 through 51095). However, Phase III did not modify the exception for payments by a physician,[12] including the parenthetical indicating that § 411.357(i) could not be used for items or services specifically excepted under § 411.357(l). We acknowledged that the expansion of the exception for fair market value compensation to items or services furnished by entities to physicians would require parties in some instances to rely on § 411.357(l) instead of § 411.357(i). We concluded, however, that upon further consideration, we believe that the required application of the fair market value compensation exception, which contains conditions not found in the less transparent exception for payments by a physician to a hospital, further reduces the risk of program abuse (72 FR 51057). We also emphasized in Phase III that the exception for payments by a physician could not be used to protect office space leases (72 FR 51044 through 51045). We explained that we did not believe that the lease of office space is an ''item or service'' and that parties seeking to protect arrangements for the rental of office space must rely on § 411.357(a) (72 FR 51059). In 2015, when we finalized the exception at § 411.357(y) for timeshare arrangements, we reaffirmed our position that the exception for payments by a physician

[12] In the September 5, 2007 **Federal Register**, the regulation text of the exception for payments by a physician was modified in error. Phase II stated that § 411.357(i) is limited to payments for items or services that are ''not specifically *excepted* by another provision in §§ 411.355 through 411.357'' (69 FR 16140). The September 5, 2007 **Federal Register** replaced ''excepted'' with ''addressed'' (72 FR 51094). The original language of the exception was restored in a correction notice to Phase III and published in the December 4, 2007 **Federal Register** (72 FR 68076).

is not available for arrangements involving the rental of office space (80 FR 71325 through 71327).

Commenters on the CMS RFI stated that our interpretation of the exception for payments by a physician, especially our determination that the exception is not available if any other exception would apply to an arrangement, unreasonably narrowed the scope of the statutory exception. Commenters also noted that compliance with other exceptions is generally more burdensome than compliance with the statutory exception for payments by a physician, and urged us to conform the language of the exception at § 411.357(i) to the statutory language at section 1877(e)(8) of the Act. As noted in the proposed rule, we found the CMS RFI comments regarding the narrowing of the statutory exception persuasive and, as a result, we reconsidered our position regarding the availability of the exception for payments by a physician for certain compensation arrangements (84 FR 55820).

To explain our proposal and the policies we are setting forth in this final rule regarding the availability of the exception at § 411.357(i), it is important to distinguish between the statutory exceptions found at section 1877(e) of the Act (codified at § 411.357(a) through § 411.357(i) of our regulations) and the regulatory exceptions (codified at § 411.357(j) *et seq.*) issued using the Secretary's authority under section 1877(b)(4) of the Act.[13] We continue to believe that the exception for payments by a physician at section 1877(e)(8) of the Act was not meant to apply to compensation arrangements that are specifically excepted by other *statutory* exceptions in section 1877 of the Act. Given the placement of the exception for payments by a physician as the final statutory exception at section 1877(e) of the Act, we believe that this exception functions as a catch-all to protect certain legitimate arrangements that are not covered by the exceptions at sections 1877(e)(1) through (7) of the Act. As a matter of statutory construction, the catch-all exception at section 1877(e)(8) of the Act does not supersede the previous exceptions. With respect to arrangements for the rental of office space or the rental of equipment, in particular, we note that the statutory exceptions for such arrangements at section 1877(e)(1) of the Act include requirements that are specific to rental arrangements, as well as general requirements that the arrangements are commercially reasonable, that rental charges are fair market value, and that compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties. We do not believe that the Congress would have imposed these particularized requirements at section 1877(e)(1) of the Act, but also allowed parties to sidestep them by relying on the exception for payments by a physician to protect rental arrangements.

Although we maintain our policy with respect to the statutory exceptions, we no longer believe that the regulatory exceptions should limit the scope of the exception for payments by a physician. Thus, we proposed to remove from § 411.357(i)(2) the reference to the regulatory exceptions, including the parenthetical referencing the exception for fair market value compensation. We also proposed that the exception at § 411.357(i) would not be available to protect compensation arrangements specifically addressed by one of the statutory exceptions, codified in our regulations at § 411.357(a) through (h). Under the proposal, parties would generally be able to rely on the exception at § 411.357(i) to protect fair market value payments by a physician to an entity for items or services furnished by the entity, even if a regulatory exception at § 411.357(j) *et seq.* may be applicable. However, for the reasons noted previously in this section II.D.9., § 411.357(i) would not be applicable to arrangements for the rental of office space or equipment.[14] That is, we believe that, as a matter of statutory construction, the exception for payments by a physician is not available to protect any type of arrangement that is specifically addressed by another statutory exception at section 1877(e) of the Act, including arrangements for the rental of office space or the rental of equipment.

We are retracting our prior statements that office space is neither an ''item'' nor a ''service.'' We made these statements, in significant part, to emphasize that we do not believe that the exception for payments by a physician should be available to protect the type of arrangement for which the Congress established a specific exception in statute. In this final rule, we have more clearly explained this position and no longer believe it is necessary to preclude office space from the categories of ''items'' and ''services.'' (We note that we have not made prior similar statements regarding equipment.) As such, and because the exception at § 411.357(i) is unavailable to protect an arrangement for the rental of office space or equipment, parties seeking to protect an arrangement for the rental of office space or equipment must structure the arrangement to satisfy the requirements of § 411.357(a), § 411.357(b), § 411.357(l) (for direct compensation arrangements), or § 411.357(p) (for indirect compensation arrangements). Although we are retracting our statement that office space is not an ''item or service,'' parties may not rely on the exception for personal service arrangements at § 411.357(d)(1) to protect arrangements for the rental of office space. We noted that § 411.357(i) may be available to protect payments by a physician for the lease or use of space that is *not* office space, such as storage space or residential real estate.

We also proposed to remove from § 411.357(i)(2) the reference to exceptions in §§ 411.355 and 411.356. As noted previously, we interpret the exception at section 1877(e)(8) of the Act for payments by a physician to function in the statutory scheme as a catch-all, to apply to compensation arrangements for the furnishing of other items or services by entities that are not specifically addressed at sections 1877(e)(1) through (7) of the Act. Therefore, we no longer believe that the exception should be limited by the exceptions at sections 1877(b) and (c) of the Act or the regulatory exceptions codified in §§ 411.355 and 411.356.

Lastly, ''items or services'' furnished by the entity under the exception for payments by a physician may not include cash or cash equivalents. That is, the physician may not make in-kind ''payments'' to the entity in exchange for cash from the entity. We believe that cash provided by an entity to a physician poses a risk of program or patient abuse, and that the Congress would have included additional safeguards at section 1877(e)(8) of the

[13] Section 1877(b)(5) of the Act directs the Secretary to establish a regulatory exception for electronic prescribing, but does not provide any statutory text or specific requirements for the exception. Pursuant to this authority, we established an exception for electronic prescribing items and services at § 411.357(v). Although § 411.357(v), unlike all the other exceptions at § 411.357(j) *et seq.,* was not issued using the Secretary's authority under section 1877(b)(4) of the Act, for purposes of our interpretation of the exception for payments by a physician, we treat § 411.357(v) as a regulatory exception. In particular, we interpret section 1877(b)(5) of the Act as a grant of authority for the Secretary to issue a regulatory exception; it is not itself a statutory exception, just as section 1877(b)(4) of the Act grants the Secretary authority to create exceptions, but is not an exception in its own right.

[14] Elsewhere in this final rule, we are finalizing our proposal to extend § 411.357(l) to arrangements for the rental of office space, including rentals of less than 1 year, provided that all the requirements of the exception are satisfied.

Act if the exception were designed to cover such arrangements. At the same time, we note that, if a physician pays an entity $10 in cash for a gift card worth $10, we do not believe that this would constitute a financial relationship for purposes of the physician self-referral law. Likewise, in cases where a physician or an entity acts as a pure pass-through, taking money from one party and passing the *exact* same amount of money to another party, we do not believe that the pass-through arrangement is a financial relationship for purposes of the physician self-referral law.

After reviewing the comments, we are finalizing our proposal at § 411.357(i) without modification.

We received the following comments and our responses follow.

Comment: Most commenters that addressed this issue supported our proposed interpretation of the statutory payments by a physician exception and the proposed regulatory changes to implement the interpretation. One commenter asserted that our previous interpretation of the statute inappropriately narrowed the utility of the exception. Other commenters emphasized that finalizing our proposal would increase flexibility and reduce the cost and burden of compliance with the physician self-referral law. Commenters generally agreed that the exception should be available to protect an arrangement even if the arrangement is addressed by a regulatory exception, but not if another statutory exception, such as the exception for the rental of office space, is applicable to the arrangement. One commenter agreed that the exception for payments by a physician functions in the statutory scheme as a ''catch-all'' exception that applies only to arrangements that are not otherwise addressed in a statutory exception.

Response: We agree with the commenters and are finalizing our revisions to § 411.357(i) as proposed.

Comment: Several commenters supported our retraction of our previous policy that office space is neither an item nor a service. The commenters recognized that, under the regulatory scheme of the physician self-referral law, retraction of the policy is key to making the exception for fair market value compensation at § 411.357(l) applicable to arrangements for the rental of office space.

Response: In this final rule, we are reiterating the retraction of our previous policy that office space is neither an item nor a service. Given our interpretation of the exception for payments by a physician within the statutory scheme of exceptions applicable only to compensation arrangements, we no longer believe that it is necessary to distinguish office space from items or services in order to ensure that the exception at § 411.357(i) may not be used for rental of office space arrangements. As recognized by the commenters and explained in section II.D.10 of this final rule, parties may now use the exception for fair market value compensation at § 411.357(l) to except arrangements for the rental of office space. At the same time, we are taking this opportunity to clarify that office space is not a service, and therefore the exception for personal service arrangements at § 411.357(d)(1) is not available to protect arrangements for the rental of office space or timeshare arrangements.

10. Exception for Fair Market Value Compensation (§ 411.357(l))

In the 1998 proposed rule, we proposed an exception at § 411.357(l) for fair market value compensation (63 FR 1699). We noted that the statutory exceptions at section 1877(e) of the Act apply to specific categories of financial relationships and do not address many common and legitimate compensation arrangements between physicians and the entities to which they refer designated health services. The exception for fair market value compensation was proposed as an open-ended exception to protect certain compensation arrangements that may not be specifically addressed in the statutory exceptions. Among other things, we stated that the exception might be used to protect arrangements for the sublease of office space (63 FR 1714). We suggested that parties could use the exception for fair market value compensation if they had any doubts about whether they met the requirements of another exception in § 411.357.

In Phase I, we finalized § 411.357(l), stating that parties could use the exception, even if another exception potentially applied to an arrangement (66 FR 919). We explained our belief that the safeguards incorporated into the exception for fair market value compensation were sufficient to cover various compensation arrangements, including arrangements covered by other exceptions. In Phase II, we responded to commenters that requested that the exception at § 411.357(l) be made available to protect arrangements for the rental of office space, including arrangements where space is rented *by* entities *to* physicians (69 FR 16111). We declined to extend § 411.357(l) to arrangements for the rental of office space, and emphasized that § 411.357(l) applied only to payments *from* an entity *to* a physician for items and services furnished by the physician. We modified our policy in Phase III and extended the application of the exception at § 411.357(l) to payments *from* a physician *to* an entity for items or services provided by the entity, but continued to decline to make § 411.357(l) applicable to an arrangement for the rental of office space (72 FR 51059 through 51060). We explained our policy at that time that the rental of office space is not an ''item or service.'' We added that, because arrangements for the rental of office space had been subject to abuse, we believe that it could pose a risk of program or patient abuse to permit parties to protect such arrangements relying on § 411.357(l). In the CY 2016 PFS final rule, we reaffirmed our position that the exception for fair market value compensation does not apply to arrangements for the rental of office space (80 FR 71327).

We have reconsidered our policy regarding the application of § 411.357(l). Through our administration of the SRDP, we have seen legitimate, nonabusive arrangements for the rental of office space that could not satisfy the requirements of § 411.357(a) because the term of the arrangement was less than 1 year, and could not satisfy the requirements of § 411.357(y) because the arrangement conveyed a possessory leasehold interest in the office space. To provide flexibility to stakeholders to protect such nonabusive arrangements, we proposed and are now finalizing modifications to § 411.357(l) to permit parties to rely on the exception for fair market value compensation to protect arrangements for the rental or lease of office space.

As discussed in many of our previous rulemakings and most recently in the CY 2017 PFS proposed rule (81 FR 46448 through 46453) and final rule (81 FR 80524 through 80534), we are concerned about potential abuse that may arise when rental charges for the lease of office space or equipment are determined using a formula based on: (1) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space (a ''percentage-based compensation formula''); or (2) per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (a ''per-click compensation formula''). We continue to believe that arrangements based on percentage compensation or per-unit of service

compensation formulas present a risk of program or patient abuse because they may incentivize overutilization and patient steering. To address this risk, in the FY 2009 IPPS final rule, we included in the exceptions for the rental of equipment, fair market value compensation, and indirect compensation arrangements restrictions on percentage-based compensation and per-click compensation formulas when determining the rental charges for the lease of equipment. Because the exception at § 411.357(l), to date, has not been applicable to arrangements for the rental of office space, it does not include a prohibition on percentage-based compensation and per-click compensation formulas when determining the rental charges for the lease of office space. (The exceptions for the rental of office space and indirect compensation arrangements currently include the prohibitions as they relate to the determination of rental charges for the lease of office space.) We remain concerned about the potential abuse related to percentage-based compensation and per-click compensation formulas for determining the rental charges of both office space and equipment. Therefore, we proposed to incorporate into the exception at § 411.357(l) prohibitions on percentage-based compensation and per-unit of service compensation formulas with respect to the determination of rental charges for the lease of office space, similar to the restrictions found in § 411.357(a)(5)(ii) and § 411.357(p)(1)(ii).

Unlike the exception for the rental of office space at § 411.357(a), the exception for fair market value compensation does not require a 1-year term. Therefore, short-term arrangements for the rental of office space of less than 1 year will be permissible under the exception. However, as with other compensation arrangements permitted under § 411.357(l), the parties will be permitted to enter into only one arrangement for the rental of the same office space during the course of a year. The parties will be able to renew the arrangement on the same terms and conditions any number of times, provided that the terms of the arrangement and the compensation for the same office space do not change. Parties are not required to renew their arrangement in writing. Renewals effectuated through course of conduct or by verbal agreement are permitted under the exception for fair market value compensation. However, parties retain the burden of proof under § 411.353(c)(2) to establish that the terms of the arrangement and the compensation for the same items, office space, or services did not change during the renewal arrangement. Although we believe that, in most cases, parties seeking to lease office space prefer leases with longer terms—for instance, to justify expenses spent on property improvements—as described by commenters, some parties, especially parties in rural areas, would prefer or find necessary the flexibility of a short-term rental of office space. Given the requirements of the exception for fair market value compensation, including the requirement that parties enter into only one arrangement for the leased office space over the course of a year and the requirement that the arrangement does not violate the anti-kickback statute, which, as explained below and in section II.D.1. of this final rule, is not being removed from § 411.357(l)(5) in the final rule, we do not believe that short-term arrangements for the rental of office space that satisfy all the requirements of § 411.357(l) pose a risk of program or patient abuse. We remind readers that, as explained in section II.D.9. of this final rule, the exception for payments by a physician at § 411.357(i) is not available to protect any leases of office space, including short-term leases.

In the proposed rule, we proposed to remove the requirement at § 411.357(l)(5) that the arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submissions. As explained in section II.D.1. of this final rule, with respect to the exception for fair market value compensation, we are finalizing this proposal with respect to Federal or State laws or regulations governing billing or claims submissions, but we are not finalizing the proposal with respect to the requirement that the arrangement does not violate the anti-kickback statute. We believe that the requirement that the arrangement does not violate the anti-kickback statute in § 411.357(l)(5) functions as an important safeguard that substitutes for certain requirements included in certain statutory exceptions but omitted from § 411.357(l), including the exclusive use requirement in the exceptions for the rental of office space and equipment. We did not propose to remove § 411.357(l)(6), which requires that any services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law. However, we solicited comments on whether this requirement is necessary to protect against program or patient abuse or should be removed from the exception, and whether substitute safeguards such as those included in many of the statutory or regulatory exceptions to the physician self-referral law would be appropriate. As explained below, in this final rule we are not removing or modifying § 411.357(l)(6).

In this final rule, we are taking the opportunity to reorganize the exception at § 411.357(l) to distinguish the writing requirement of the exception for fair market value compensation from other requirements. As the exception is currently organized, § 411.357(l)(1) requires the arrangement to be in writing and requires the writing to specify the items or services covered by the arrangement; § 411.357(l)(2) requires the timeframe of the arrangement to be in writing, and also contains substantive requirements pertaining to timeframe of the arrangement and rules governing the frequency with which parties can enter into an arrangement for the same items or services; § 411.357(l)(3) requires the compensation of the arrangement to be in writing, and also contains substantive requirements pertaining to the compensation under the arrangement. We are placing the writing requirement from these various provisions in § 411.357(l)(1). Specifically, § 411.357(l)(1) will require the arrangement to be in writing and signed by the parties; while § 411.357(l)(i) through § 411.357(l)(iii) will list the information that must be specified in writing, as follows: The items, services, office space, or equipment covered by the arrangement (§ 411.357(l)(1)(i)); the compensation that will be provided under the arrangement (§ 411.357(l)(1)(ii)); and timeframe of the arrangement (§ 411.357(l)(1)(iii)). These organizational modifications are intended to clarify the exception and do not affect or modify the requirements of the exception in any way.

In addition to the organizational changes explained above, after reviewing the comments, we are finalizing our proposal to permit arrangements for the lease of office space under § 411.357(l) with certain modifications to clarify the exception and to protect against program or patient abuse. First, we are clarifying in the introductory chapeau language that the exception may be used for the *lease* of office space and not only for the *use* of office space. Second, we are no longer requiring at § 411.357(l)(5) that the arrangement not violate any Federal or State law or regulation governing billing or claims submission, but we are not

finalizing our proposal to remove the requirement for compliance with the anti-kickback statute. Third, we are adding the phrase ''even if no referrals were made between the parties'' to the commercially reasonable requirement in § 411.357(l)(4). Fourth, as explained in section II.E.1. of this final rule, we are modifying the requirement at § 411.357(l)(2) to permit parties to rely on § 411.357(l) and § 411.357(z) to protect an arrangement for the same items, services, office space, or equipment during the course of a year. Lastly, as explained in section II.B.4, we are requiring at § 411.357(l)(7) that any arrangement that includes a directed referral requirement must satisfy all the conditions of § 411.354(d)(4).

We received the following comments and our responses follow.

Comment: Commenters generally supported our proposal to allow parties to rely on the exception for fair market value compensation at § 411.357(l) to protect arrangements for the rental of office space. Commenters recognized the flexibility afforded by the proposal, especially for office space leases with a term of less than one year. One commenter noted that the proposal would be helpful for rural providers, where short-term rentals may be necessary to address community needs, such as the need to relocate a physician due to facility demands or renovations. Another commenter stated that the exception could be helpful for situations where a laboratory leases space from a physician for a temporary patient service center for specimen collections while a permanent space is renovated or constructed.

Response: We agree with the commenters that the proposal, once finalized, will afford greater flexibility for short-term leases of office space. Under the current regulations, an arrangement for the *lease* of office, which involves the transfer of dominion and control of the leased premises to the lessee, must have a term of at least 1 year. On the other hand, arrangements for the use of space, where dominion and control over the space are not transferred to the party making use of the space, are permitted for durations of less than 1 year under the exception for timeshare arrangements at § 411.357(y). (*See* 80 FR 71325 through 71326). However, the exception at § 411.357(y) includes several requirements not found in the exception for the rental of office space at § 411.357(a), such as a requirement at § 411.357(y)(2) that the arrangement is between a physician and a hospital or a physician organization and the requirement at § 411.357(y)(3)(i) that the premises covered by the arrangement is used predominantly for evaluation and management services to patients. Given the latter restrictions, an arrangement such as that identified by the commenter, under which a laboratory compensates a physician for space used on a short-term basis for specimen collections, would not be permissible under either § 411.357(a) or § 411.357(y). As modified in this final rule, the exception for fair market value compensation at § 411.357(l) may be used to except such an arrangement, provided that all the requirements of the exception are satisfied. To clarify that the exception at § 411.357(l) may be used for *leases* of office space, where dominion and control are transferred to the lessee, we are modifying the chapeau language of the exception to include the phrase ''lease of office space.''

Comment: Commenters generally opposed inclusion of a requirement for compliance with the anti-kickback statute in regulatory exceptions, including the exception for fair market value compensation at § 411.357(l). One commenter that addressed our request for comments on § 411.357(l)(6), which prohibits services furnished under an arrangement from involving the counseling or promotion of a business arrangement or other activity that violates a Federal or State law, specifically objected to including a requirement for compliance with the anti-kickback statute in the exception for fair market value compensation.

Response: As explained in section II.D.1 of this final rule, we are not removing the requirement for compliance with the anti-kickback statute from the exception for fair market value compensation at § 411.357(l)(5). We believe that the requirement that the arrangement does not violate the anti-kickback statute in § 411.357(l)(5) functions as an important substitute safeguard for requirements that are included in certain statutory exceptions but omitted from § 411.357(l), including the exclusive use requirement in the exceptions for the rental of office space and equipment. For similar reasons, we are also not removing the requirement at § 411.357(l)(6), which requires that the services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law. This requirement applies to service arrangements and is carried over from the statutory exception for personal service arrangements, codified in our regulations at § 411.357(d)(1)(vi). We are concerned that, if we remove the requirement at § 411.357(l)(6), we would need to include additional safeguards to substitute for the statutory requirements in order to ensure that excepted service arrangements under § 411.357(l) do not pose a risk of program or patient abuse.

Comment: One commenter supported removing the phrase ''and furthers the legitimate business purpose of the parties'' from § 411.357(l)(4), but requested either that the term ''commercially reasonable'' be defined to include a requirement that the arrangement must be commercially reasonable *even if no referrals were made between the parties* or that § 411.357(l)(4) be modified to require an arrangement to be commercially reasonable ''even if no referrals were made between the parties.''

Response: As we discussed in section II.B.2, we are not including the ''even if no referrals were made'' requirement in the *definition* of ''commercially reasonable'' at final § 411.351. Most exceptions that include a commercial reasonableness requirement, including exceptions that apply to arrangements that could also be excepted by § 411.357(l), stipulate that the arrangement must be commercially reasonable ''even if no referrals'' were made between the parties. We are adopting the second approach advocated by the commenter and are revising the requirement at § 411.357(l)(4) to clarify that the arrangement must be commercially reasonable ''even if no referrals were made between the parties.'' Without this modification, some stakeholders may believe that the standard articulated at § 411.357(l) is a different and less demanding standard than the requirement in other exceptions.

Comment: One commenter supported our proposal at § 411.357(l)(3) to prohibit the use of percentage-based or per-unit-of service based compensation formulas for determining the compensation for the rental of office space under the exception for fair market value compensation.

Response: We are finalizing this proposal. We believe that it is a necessary safeguard for the reasons stated in the CY 2017 PFS proposed rule (81 FR 46448 through 46453) and final rule (81 FR 80524 through 80534).

Comment: One commenter requested that CMS permit indefinite holdovers for arrangements under the exception for fair market value compensation, similar to the indefinite holdover provisions in the exceptions for rental of office space, rental of equipment, and personal service arrangements. The commenter noted that an arrangement may be for any period of time under

§ 411.357(l), and the exception permits the arrangement to be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change. The commenter interpreted the renewal provision under § 411.357(l) to require written documentation that the renewed arrangement was on the same terms and conditions, while there is no such requirement under the indefinite holdover provisions.

Response: We believe that the commenter misunderstood the renewal provision in § 411.357(l)(2). Under § 411.357(l)(2), parties are permitted to renew an arrangement any number of times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change. Likewise, the indefinite holdover provisions at § 411.357(a)(7), § 411.357(b)(6), and § 411.357(d)(1)(vii) require the holdover arrangement to continue on the same terms and conditions. Neither the indefinite holdover provisions in the latter exceptions nor the renewal provision in § 411.357(l)(2) require the holdover arrangement or renewal arrangement to be documented in a formal writing. To be sure, parties renewing an arrangement under § 411.357(l)(2) retain the burden of proof under § 411.353(c)(2) to establish that the renewal arrangement is on the same terms and conditions as the previous arrangement, but parties to a holdover arrangement under one of the indefinite holdover provisions have a similar burden. In sum, with respect to documentation and writing requirements, there is no substantive difference between the indefinite holdover provisions and the renewal provision in § 411.357(l)(2). Therefore, we are not including an indefinite holdover provision in § 411.357(l).

11. Electronic Health Records Items and Services (§ 411.357(w))

Relying on our authority at section 1877(b)(4) of the Act, on August 8, 2006, we published a final rule (the 2006 EHR final rule) that, among other things, established an exception at § 411.357(w) for certain arrangements involving the donation of interoperable electronic health records software or information technology and training services (the EHR exception) (71 FR 45140). The EHR exception was initially set to expire on December 31, 2013. On December 27, 2013, we published a final rule (the 2013 EHR final rule) modifying the EHR exception by, among other things, extending the expiration date of the exception to December 31, 2021, excluding laboratory companies from the types of entities that may donate electronic health records items and services under the exception, and updating the provision under which electronic health records software is deemed interoperable (78 FR 78751).

Although we did not specifically request comments on the EHR exception in the CMS RFI, we received several comments related to the exception. In addition, in its August 27, 2018 request for information described in section I.B.1. of this final rule, OIG requested comments on the safe harbor at 42 CFR 1001.952(y), which is substantively similar to the EHR exception at § 411.357(w) (*see* 83 FR 43607). After reviewing comments related to the EHR exception and safe harbor submitted in response to the CMS RFI and the OIG's request for information, as well as recent statutory and regulatory developments arising from the 21st Century Cures Act (Pub. L. 114–255, enacted on December 13, 2016) (Cures Act), in the proposed rule, we proposed to update provisions in the EHR exception pertaining to interoperability (§ 411.357(w)(2)) and data lock-in (§ 411.357(w)(3)), clarify that donations of certain cybersecurity software and services are permitted under the EHR exception, remove the sunset provision at § 411.357(w)(13), and modify the definitions of ''electronic health record'' and ''interoperable'' at § 411.351 to ensure consistency with the Cures Act (84 FR 55822). We also proposed to modify the requirement at § 411.357(w)(4) that a physician contributes at least 15 percent of the cost of the donated electronic health records items and services and permit certain donations of replacement electronic health records items and services (84 FR 55822).

As discussed more fully below, in this final rule we are finalizing certain of our proposals to revise the EHR exception. Despite the fundamental differences in the statutory structure, operation, and penalties of the respective underlying statutes, we have worked closely with OIG to ensure consistency between our revised EHR exception and the policies finalized by OIG related to its safe harbor and discussed elsewhere in this issue of the **Federal Register**.

a. Requirements Regarding Interoperability

Currently, the requirements at § 411.357(w)(2) and (3) require donated software to be interoperable and prohibit the donor (or a person on the donor's behalf) from taking action to limit the interoperability of the donated items or services. In the proposed rule (84 FR 55822), we proposed changes that would impact § 411.357(w)(2) and (3) based on the Cures Act and the Office of the National Coordinator for Health Information Technology (ONC), HHS Notice of Proposed Rulemaking, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (ONC NPRM), which proposed to implement key provisions in Title IV of the Cures Act.[15] Among other things, the ONC NPRM proposed Conditions and Maintenance of Certification requirements for health IT developers under the ONC Health IT Certification Program (certification program) and proposed to define reasonable and necessary activities that do not constitute information blocking for purposes of section 3022(a)(1) of the Public Health Service Act (PHSA). We discuss our specific proposals and our final policies and regulations pertaining to § 411.357(w)(2) and (3) below in subsections (1) and (2), respectively.

(1) The ''Deeming Provision'' (§ 411.357(w)(2))

The existing regulation at § 411.357(w)(2) requires that software donated under the EHR exception is interoperable. The deeming provision at § 411.357(w)(2) provides certainty to parties that donated software satisfies the interoperability requirement at § 411.357(w)(2). Specifically, § 411.357(w)(2) currently provides that software is deemed to be interoperable if it has been certified under ONC's certification program to electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. In the 2013 EHR final rule, we modified the deeming provision to reflect developments in the ONC certification program and to track ONC's anticipated regulatory cycle. By relying on ONC's certification program and related updates of criteria and standards, we stated that the deeming provision would meet our objective of ensuring that software is certified to the current required standard of interoperability when it is donated (78 FR 78753). In the proposed rule, we proposed to retain this general construct for the updated EHR exception, but proposed two clarifications to the deeming provision at § 411.357(w)(2) (84 FR 55823). Our current regulation at § 411.357(w)(2) specifies that the software is deemed to be interoperable if, on the date it is provided to the physician, it has been certified by a

[15] 84 FR 7424 (March 4, 2019). At the time our proposed rule was published on October 17, 2019, ONC had not yet issued its final rule implementing the Cures Act. ONC published its final rule on May 1, 2020 (85 FR 25642).

certifying body to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. We proposed to modify this language to replace the phrase ''has been certified'' with the phrase ''is certified'' (84 FR 55823). The proposed modification was intended to clarify that the certification must be current as of the date of the donation, as opposed to the software having been certified at some point in the past (and potentially no longer maintaining certification on the date of the donation). We also proposed to remove the reference to ''an edition'' of certification criteria to align with changes to ONC's certification program (84 FR 55823). As we describe in more detail below, we proposed and are finalizing an updated definition of ''interoperable'' (84 FR 55824 through 55825). Although the revised definition would not require a change to the text of § 411.357(w)(2), the revision would impact the deeming provision, and we solicited comments regarding this update to the definition of ''interoperable'' (84 FR 55823). We emphasized in the proposed rule and reaffirm here that an arrangement for the donation of software that met the definition of interoperable and that satisfied the requirements of § 411.357(w) at the time the donation was made will not cease to be protected by the exception, even though we are finalizing certain changes to these provisions (84 FR 55823).

After reviewing comments on our proposal, we are finalizing our clarifying revisions to the deeming provision at § 411.357(w)(2) as proposed, with one modification to the regulation text. We are removing the phrase ''electronic health record'' preceding ''certification criteria'' because the phrase ''electronic health records certification criteria'' has been removed from 45 CFR part 170 as of June 30, 2020.

We received the following comments and our responses follow.

Comment: Commenters generally agreed with our proposal to clarify that software would be deemed to be interoperable under § 411.357(w)(2) if, on the date it is donated, it ''is'' certified by a certifying body authorized by ONC, rather than ''has been certified.'' Some commenters had questions about our removal of the phrase ''an edition'' before ''the electronic health record certification criteria'' and inquired whether we should specify that the criteria are the ''latest'' or ''current'' certification criteria. One commenter recommended that we modify the deeming provision to state that the certification must be current as of the date that the donor has entered into a binding agreement with the recipient or the electronic health records vendor. This commenter stated that a reasonable time limit, such as 1 year, could be applied in order to prevent potential fraud or abuse.

Response: We are finalizing our proposal to modify § 411.357(w)(2) to specify that the donated software ''is'' certified on the date that it is donated, as opposed to ''has been certified'' on that date, and to delete the phrase ''an edition.'' We agree that the certification criteria should be the latest or current criteria; that is, current as of the date of donation. However, we believe that our proposal, which provides that the software must be certified to the ''then-applicable'' version of 45 CFR part 170, already includes this requirement, and we are finalizing the regulation text as proposed. As noted above, we are removing the phrase ''electronic health record'' before ''certification criteria'' in § 411.357(w)(2), because the phrase ''electronic health records certification criteria'' has been removed from 45 CFR part 170 as of June 30, 2020. We note that the latter change does not alter the scope of the remuneration to which the EHR exception applies. The exception continues to apply only to donations of items or services that are necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records. We also decline to adopt the commenter's suggestion that the certification must be current on the date that the donor has entered into a binding agreement with the recipient. To help ensure that donations of health information technology will further the policy goal of fully interoperable health information systems (71 FR 45149), we believe that parties that enjoy the benefit of donated software being deemed to be interoperable must ensure that it is certified to the current certification criteria on the date it is donated. However, depending on the facts and circumstances, donations that do not satisfy the requirements of the deeming provision may still satisfy the requirement at § 411.357(w)(2) that the donated software is interoperable.

Comment: One commenter opposed the concept of an ''optional'' deeming provision, asserting that it is critical to require that software be certified by a certifying body authorized by ONC to further support the goal of value-based arrangements. In contrast, another commenter was concerned that the EHR exception applies only to donations of software that has been certified by ONC.

Response: Although we agree that the interoperability of software is a critical requirement of the EHR exception, we disagree with the first commenter that certification by a certifying body authorized by ONC should be the only way of meeting this requirement. This certification provides donors and recipients with assurance that the electronic health records software donated under their arrangement is interoperable for purposes of the EHR exception, but such certification is not required under the exception. We emphasize that the exception does not require that donated software is certified as interoperable by a certifying body authorized by ONC; rather, the exception requires that donated software is interoperable. We believe that requiring only that donated software is interoperable—allowing parties to demonstrate that donated software is interoperable even if it is not certified as interoperable by a certifying body authorized by ONC—coupled with the optional method for assuring that software is interoperable through satisfaction of the deeming provision at § 411.357(w)(2), affords parties sufficient flexibility under the exception for donations of electronic health records items or services.

Comment: One commenter suggested that the proposed change to the deeming provision creates compliance uncertainty in the context of an ongoing software donation. In particular, the commenter was concerned that the proposed wording change would mean that, if at any time after the initial software donation the electronic health records software loses its certification, the continued provision of the software, including maintenance, would implicate the fraud and abuse laws. Other commenters supported the proposal to require that software is certified at the time it is provided to a recipient, with one commenter noting that any updates to donated systems should also need to be certified to the most recent standards. Another commenter requested that we provide for a 5-year grace period under the interoperability deeming provision so that physicians not participating in the Quality Payment Program could continue to use donated electronic health records software certified to the 2015 edition.

Response: As we explained in response to the comment immediately above, the deeming provision is optional. Certification of donated electronic health records software by a certifying body authorized by ONC is not required to satisfy the requirement at § 411.357(w)(2) that the software is interoperable, as defined at § 411.351; the exception merely requires that the

software is interoperable at the time it is provided to the recipient. Regardless of whether the physician recipient participates in the Quality Payment Program, electronic health records software is not required to satisfy the deeming provision at § 411.357(w)(2) in order to be ''interoperable'' as defined at § 411.351. With respect to ongoing donations of maintenance, updates, or other items or services in connection with previously donated electronic health records software, we note the following. If the electronic health records software loses its certification, then new donations of that electronic health records software, including updates and patches of that software, will not be *deemed* to be interoperable under the deeming provision in § 411.357(w)(2). However, if the electronic health records software is still interoperable (as defined at § 411.351), then the EHR exception will remain available to protect ongoing donations of such electronic health records software, including updates and patches, provided that all other requirements of the exception are satisfied. If, on the other hand, software that loses its certification is no longer interoperable (as defined at § 411.351), then new donations of such electronic health records software, including updates and patches of the software, would not be protected under the EHR exception.

(2) Information Blocking and Data Lock-in (§ 411.357(w)(3))

The current requirement at § 411.357(w)(3) prohibits the donor (or any person on the donor's behalf) from taking any action to limit or restrict the use, compatibility, or interoperability of the donated items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health IT applications, products, or services). Beginning with the 2006 EHR final rule and reaffirmed in the 2013 EHR final rule, § 411.357(w)(3) has been designed to: (1) Prevent the misuse of the exception that results in data and referral lock-in; and (2) encourage the free exchange of data (in accordance with protections for privacy) (78 FR 78762). Since the publication of the 2006 EHR final rule and 2013 EHR final rule, significant legislative, regulatory, policy, and other Federal government action further defined the data lock-in problem (now commonly referred to as ''information blocking'') and established penalties for certain types of individuals and entities that engage in information blocking. Most notably, the Cures Act added section 3022 of the PHSA, known as ''the information blocking provision,'' which defines conduct that constitutes information blocking by health care providers, health IT developers of certified health IT, health information exchanges, and health information networks. Section 3022(a)(1) of the PHSA defines ''information blocking'' in broad terms, while section 3022(a)(3) of the PHSA authorizes and charges the Secretary to identify reasonable and necessary activities that do not constitute information blocking for purposes of section 3022(a)(1) of the PHSA. The ONC NPRM included proposals to implement the statutory definition of ''information blocking,'' define certain terms related to the statutory definition of ''information blocking,'' and establish exceptions to the definition of ''information blocking.'' ONC published its final rule on May 1, 2020 (85 FR 25642).

In the proposed rule, we proposed modifications to § 411.357(w)(3) to recognize these significant updates since the 2013 EHR final rule (84 FR 55823). Specifically, we proposed at § 411.357(w)(3) to prohibit the donor (or any person on the donor's behalf) from engaging in a practice constituting information blocking, as defined in section 3022 of the PHSA, in connection with the donated items or services. We stated that, should ONC finalize its proposals to implement section 3022 of the PHSA at 45 CFR part 171, we would incorporate such regulations into the requirement at § 411.357(w)(3) for purposes of the physician self-referral law, if we finalized the proposals described in the proposed rule (84 FR 55823).

We noted in the proposed rule that the current requirements of the EHR exception, while not using the term ''information blocking,'' already include concepts similar to those found in the Cures Act's prohibition on information blocking (84 FR 55823). For example, in prior rulemaking, we stated our concern about donors (or those on the donor's behalf) taking steps to limit the interoperability of donated software to lock in or steer referrals (*see,* for example, 71 FR 45156 and 78 FR 78762 through 78763). We stated in the proposed rule that the proposed modifications of § 411.357(w)(3) were not intended to change the underlying purpose of this requirement, but instead further our longstanding goal of preventing abusive arrangements that lead to information blocking and referral lock-in through modern understandings of those concepts established in the Cures Act (84 FR 55823).[16] We solicited comments on aligning the requirement at § 411.357(w)(3) with the PHSA information blocking provision and the information blocking definition in 45 CFR part 171.

After reviewing comments on our proposal, we are not finalizing the proposed modification of § 411.357(w)(3). Rather, based on the comments and for the reasons explained below, we are removing § 411.357(w)(3) from our regulations.

We received the following comments and our responses follow.

Comment: We received a number of comments about incorporating the ''information blocking'' prohibitions from the Cures Act or the ONC NPRM into the EHR exception at § 411.357(w)(3). Several commenters supported aligning the EHR exception with the concepts of interoperability and information blocking from the Cures Act and the ONC NPRM, including our proposal to expressly prohibit information blocking at § 411.357(w)(3). One commenter agreed with CMS' assessment that the incorporation of the concept of information blocking into the regulation does not change the underlying purpose of the existing interoperability requirements. Another commenter that supported the prohibition on information blocking asserted that large health systems can control referrals and increase market share by limiting access to patients' records to specific providers on the same health information network, thereby shutting out independent providers and negatively impacting patient care. Other commenters did not disagree that information blocking should be prohibited, but raised a number of questions and concerns regarding how such a provision would work in the EHR exception. For example, a number of commenters expressed concern about relying on the ONC NPRM, which was not yet final at the time our proposed rule was published. Some commenters were particularly concerned about the array of exceptions to the definition of ''information blocking'' and incorporation of the definition of ''electronic health information'' as proposed in the ONC NPRM.

Some commenters asked that we clarify which party is responsible to ensure that information blocking does not occur, asserting that a donor cannot

[16] We recognized in the proposed rule that the ONC NPRM was not a final rule and was subject to change (84 FR 55823). However, we based our proposals on both the statutory language and the language in ONC's NPRM for purposes of soliciting public input on our proposals.

control what happens to software after it is donated. Several commenters recommended removing or revising the requirement in the EHR exception that a donor (or any person on a donor's behalf) does not engage in a practice constituting information blocking, explaining that a vendor may engage in information blocking without the donor's knowledge. Another commenter expressed concern that, if a determination of information blocking against either a donor or recipient occurs at some time after the donation, the recipient may be vulnerable to unexpected costs or loss of access to its health information technology if the arrangement suddenly ends. Another commenter asserted that the incorporation of ONC's proposals into the exception at § 411.357(w)(3) would introduce an intent-based requirement into the strict-liability framework of the physician self-referral law.

A few commenters suggested that, rather than including a prohibition on information blocking (as that term is defined in the Cures Act or in 45 CFR part 171) as a requirement of the EHR exception, CMS should assume that information blocking will not be tolerated and will be enforced through other authorities. One commenter explained that, when the EHR exception was first issued in 2006, interoperability was in its infancy, and there was no separate regulatory guidance on interoperability and information blocking, whereas now these concepts are separately addressed and regulated by ONC. Given these changes, the commenters maintained that incorporation of information blocking provisions into the EHR exception is duplicative and unnecessary.

Response: Based on the comments and after assessing the final rule published by ONC, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (ONC final rule),[17] we are removing the requirement at § 411.357(w)(3) in its entirety. This requirement, when originally implemented in the 2006 EHR final rule, was intended to ''help ensure that donations of health information technology will further the policy goal of fully interoperable health information systems and will not be misused to steer business to the donor.'' (71 FR 45156). The 2013 EHR final rule also explained that the Department was considering other policies to improve interoperability and noted that those policy efforts are ''better suited than this exception to consider and respond to evolving functionality related to the interoperability of electronic health record technology'' (78 FR 78763). At that time, the Department had few other authorities to directly address information blocking. However, there are now other enforcement authorities designed to address information blocking. For example, the Cures Act gave ONC and OIG more direct authority to address information blocking. Additionally, CMS has separate authority to address providers that information block, and OCR has authorities related to patient access.

The Cures Act and the ONC final rule recognize that certain practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information may nonetheless be reasonable and necessary. That is why the Cures Act directed the Secretary to identify exceptions to the definition of information blocking. The ONC final rule implements eight exceptions that apply to practices likely to interfere with the access, exchange, or use of electronic health information provided that the practice meets the conditions of an exception. However, § 411.357(w)(3), as implemented by the 2006 EHR final rule, required that a party not take ''any action to limit or restrict the use, compatibility, or interoperability'' of the donated electronic health records items or services. The requirement did not account for actions that may be reasonable and necessary, such as implementing privacy and security measures.

Recognizing the developments since 2013, we agree with the commenter that newer and separate authorities are better suited than a requirement of an exception to the physician self-referral law to deter information blocking and hold individuals and entities that engage in information blocking appropriately accountable. We also agree with commenters that a recipient is unlikely to have the capabilities to determine if a donor (or someone on the donor's behalf) engaged in information blocking, which includes a level of intent set by statute, or met an exception to information blocking as set forth in the ONC final rule. Given these potential issues with the proposed modifications to § 411.357(w)(3) and limitations of the original requirement at § 411.357(w)(3) discussed above, we no longer believe that the requirement is an effective way to achieve the policy goals that served as its original basis. Removing the requirement at § 411.357(w)(3) should sufficiently address the concerns of the commenters that had questions about the scope of information blocking practices, how CMS would determine the party responsible, and how the information blocking knowledge standards in the Cures Act and ONC final rule would be assessed in context of this exception and the strict-liability framework of the physician self-referral law. We emphasize that we are maintaining the interoperability requirement at § 411.357(w)(2). We believe that this requirement and the optional deeming provision at § 411.357(w)(2) will ensure that donations of items and services under § 411.357(w) that satisfy all the requirements of the EHR exception further the Department's policy goal of an interoperable health system and prevent donations of items and services intended to lock in referrals by limiting the flow of electronic health information.

Comment: One commenter requested that we include in the EHR exception a requirement that donors must also provide access to electronic health records to pharmacists. The commenter stated that some health information technology systems block pharmacists' visibility into relevant clinical information from other health care providers.

Response: The EHR exception does not limit the scope of permissible donors to those donors that grant access to electronic health records to a specified set of providers or suppliers. However, for a donation to be permissible under the EHR exception, among other things, the software must be interoperable and should not inappropriately interfere with, prevent, or materially discourage legally permissible access, exchange, or use of relevant clinical information. We encourage parties to report concerns regarding potential information blocking to *https://healthit.gov/report-info-blocking*.

b. Cybersecurity

We proposed to amend the EHR exception to clarify that the exception is applicable (and always has been applicable) to certain cybersecurity software and services,[18] and to more broadly protect the donation of software and services related to cybersecurity (84 FR 55823). Currently, the exception at § 411.357(w) protects electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive

[17] 85 FR 25642 (May 1, 2020).

[18] For instance, a secure log-in or encrypted access mechanism included with an EHR system or EHR software suite would be cybersecurity features of the EHR items or services that may be protected under the existing EHR exception.

electronic health records. We proposed to modify this language to expressly include software that ''protects'' electronic health records, and to expressly include software and services related to cybersecurity.

In the 2006 EHR final rule, we emphasized that software and information technology and training services donated under § 411.357(w) must create, maintain, transmit, or receive electronic health records, and those functions must predominate (71 FR 54151). We stated that the core functionality of the items and services must be the creation, maintenance, transmission, or receipt of individual patients' electronic health records, but, recognizing that electronic health records software is commonly integrated with other features, we also stated that arrangements in which the software package included other functionality related to the care and treatment of individual patients would be protected (71 FR 45151). Under our proposal, the same criteria would apply to cybersecurity software and services, provided that the predominant use of the software or services is cybersecurity associated with the electronic health records.

In section II.E.2. of this final rule, we discuss the new exception at § 411.357(bb), which applies specifically to arrangements involving the donation of cybersecurity technology and related services (the cybersecurity exception), and the definition of ''cybersecurity'' at § 411.351 that will apply to both the EHR exception and the cybersecurity exception at § 411.357(bb). As finalized, the cybersecurity exception at § 411.357(bb) is broader and includes fewer requirements than the EHR exception as applied to cybersecurity software and services that are necessary and used predominantly to protect electronic health records. Among other things, the cybersecurity exception at final § 411.357(bb) does not require recipients to contribute to the cost of the donated cybersecurity technology or services, while the EHR exception retains the cost contribution requirement at § 411.357(w)(4) for donations of electronic health records items or services. In the proposed rule, we solicited comments on whether it is necessary to modify the EHR exception to expressly include cybersecurity, given our proposed addition of a standalone exception for cybersecurity technology and related services at § 411.357(bb), and we stated that a party seeking to protect an arrangement involving the donation of cybersecurity software and services only needs to comply with the requirements of one applicable exception (84 FR 55824).

After reviewing the comments on our proposed rule, we are finalizing our proposal to expand the EHR exception to expressly include cybersecurity software and services so that it is clear that an entity donating electronic health records software and providing training and other related services may also utilize the EHR exception to protect donations of related cybersecurity software and services to protect the electronic health records, provided that all the requirements of the EHR exception are satisfied. In the final exception, we removed the word ''certain'' before ''cybersecurity software and services'' in the introductory chapeau language to avoid ambiguity regarding the scope of the EHR exception.

We received the following comments and our responses follow.

Comment: A number of commenters supported stating in regulation text that the EHR exception applies to donations of cybersecurity software and services that protect electronic health records. These commenters stated that the proposal, if finalized, would clarify the regulations, and one of the commenters also noted that the revision would reduce administrative overhead by avoiding real or perceived disparities between donations of electronic health records items and services and cybersecurity donations. One commenter supported our proposal to include certain cybersecurity donations under the EHR exception, as well as in proposed § 411.357(bb). The commenter appreciated our statement that cybersecurity donations only need to satisfy one of the exceptions, and noted that having two exceptions available allows a donor to tailor its donation strategy.

Response: We are finalizing our proposal to expressly permit donations of cybersecurity software and services that protect electronic health records under the EHR exception. We agree with the commenter that having two exceptions available to protect donations of cybersecurity software and services increases flexibility under our regulations.

Comment: A few commenters expressed concern that the proposal related to cybersecurity software and services with respect to the EHR exception and the separately proposed cybersecurity exception at § 411.357(bb) overlap significantly and could lead to confusion if both are finalized. The commenters stated that, if CMS finalizes a separate cybersecurity exception at § 411.357(bb), the proposed cybersecurity-related clarifications to the EHR exception would not be necessary. One of the commenters questioned how the cost contribution requirement under the EHR exception at § 411.357(w)(4) would apply to donations of cybersecurity software under § 411.357(w), given that there is no cost contribution requirement in the cybersecurity exception at proposed § 411.357(bb), and also asked whether the electronic health records or cybersecurity function must predominate in software that includes both electronic health records and cybersecurity functions. A different commenter requested that, if we finalize protection for certain cybersecurity software and services under the EHR exception, we also clarify that the predominant purpose of the software or service must be cybersecurity associated with electronic health records. Another commenter suggested that creating separate exceptions for electronic health records items and services and cybersecurity technology and related services is taking a piecemeal approach to tools that must work together for care coordination.

Response: We recognize that there is a certain amount of overlap between the cybersecurity exception established in this final rule at § 411.357(bb) and the EHR exception, as amended by this final rule, although we do not agree that this overlap will result in the type of confusion suggested by the commenter. The revision to the introductory language of § 411.357(w) merely confirms in regulation text that the EHR exception has always been applicable to (and remains applicable to) arrangements that include the donation of cybersecurity software and services that have a predominant purpose of protecting electronic health records. In application, if a party is donating electronic health records items and services under the EHR exception, and the donation includes cybersecurity software or services that are necessary and used predominantly to protect electronic health records, the parties may structure their entire arrangement to satisfy the requirements of the EHR exception, instead of structuring the arrangement to satisfy two different exceptions. We believe that having this option available will reduce administrative burden for some parties. Other parties may wish to structure such donations as two separate arrangements that each satisfy the requirements of the respective exception at § 411.357(w) and § 411.357(bb). As noted in the proposed rule and reiterated above, parties seeking to

protect an arrangement involving the donation of cybersecurity software and services only need to satisfy the requirements of one applicable exception (84 FR 55824).

Regarding the requirement in the EHR exception that a physician recipient must contribute 15 percent of the donor's cost of the donated items and services, under this final rule, the EHR exception retains the 15 percent cost contribution requirement at § 411.357(w)(4), but there is no cost contribution requirement under the standalone cybersecurity exception at § 411.357(bb). Thus, if parties rely on the exception at § 411.357(w) to protect an arrangement for a donation that includes both electronic health records items and services and related cybersecurity software or services, the physician recipient must contribute 15 percent of the donor's cost for the cybersecurity software or services under § 411.357(w)(4). If parties structure such a donation to satisfy the requirements of § 411.357(w) and § 411.357(bb) respectively, then the physician does not have to pay the 15 percent cost contribution for the cybersecurity software and services if the arrangement related to the cybersecurity software and services satisfies all the requirements of § 411.357(bb).

We reiterate here that, with respect to cybersecurity technology and related services, the scope of the EHR exception is more limited than the standalone cybersecurity exception at § 411.357(bb). Arrangements for the donation of standalone cybersecurity hardware or items or services that are not used predominantly to protect electronic health records (but are used predominantly to implement, maintain, or reestablish cybersecurity) are not excepted under the EHR exception, but may be protected under the cybersecurity exception if all the requirements of § 411.357(bb) are satisfied.

Comment: Some commenters requested that CMS broaden the application of the EHR exception to additional cybersecurity technology and services, for example, to cybersecurity hardware, such as network appliances. One commenter requested that we make the EHR exception applicable to donations of cybersecurity hardware, software, infrastructure and services, without exception and without a requirement that the recipient contribute 15 percent of the donor's cost for the items or services. Another commenter suggested that, if the expanded exception does not protect hardware, CMS should permit donors to place cybersecurity hardware at the recipient's location as long as the donor retains title to or a leasehold interest in the equipment.

Response: By including the word ''protect'' in the introductory chapeau language of § 411.357(w), we are clarifying that the scope of the EHR exception applies to cybersecurity software or other information technology and training services that are necessary and used predominantly to protect electronic health records. We decline to expand the EHR exception to apply to additional services or hardware, including hardware that is donated or loaned to a recipient. There is a separate, standalone exception at final § 411.357(bb) that applies to broader cybersecurity donations, including donations of cybersecurity hardware, and that exception does not include a contribution requirement.

c. The Sunset Provision

The EHR exception originally was scheduled to expire on December 31, 2013. In the 2006 EHR final rule, we stated that the need for an exception for donations of electronic health records items and services should diminish substantially over time as the use of electronic health records technology becomes a standard and expected part of medical practice. In our 2013 proposal to revise the EHR exception (78 FR 21308), we recognized that, although the adoption of electronic health records had risen dramatically, its use was not yet universal nationwide. Because continued adoption of electronic health records remained an important goal of the Department, we solicited comments regarding an extension of the EHR exception (78 FR 21311 through 21312). In response to those comments, in the 2013 EHR final rule, we extended the sunset date of the exception to December 31, 2021, a date that corresponds to the end of the electronic health records Medicaid incentives (78 FR 78755 through 78757). We stated our continued belief that, as progress on the goal of nationwide electronic health records adoption is achieved, the need for an exception for donations should continue to diminish over time. Nonetheless, commenters on the CMS RFI and on OIG's request for information requested that we make the EHR exception and safe harbor permanent.

Although widespread (though not universal) adoption of electronic health records largely has been achieved at this time, we no longer believe that the need for an exception for arrangements involving the donation of electronic health records items and services will diminish over time or completely disappear. The continued availability of the EHR exception provides certainty with respect to the contribution costs related to donations of electronic health records items and services for recipients, facilitates adoption by physicians who are new entrants into medical practice or have postponed adoption based on financial concerns regarding the ongoing costs of maintaining and supporting an electronic health records system, and helps preserve the gains already made in the adoption of interoperable electronic health records technology (84 FR 55824). Therefore, in the proposed rule, we proposed to eliminate the sunset provision at § 411.357(w)(13) (84 FR 55824). In the alternative, we considered an extension of the sunset date. We sought comment on whether we should extend the sunset date instead of making the exception permanent, and if so, the duration of any such extension. Based on the comments we received on the proposed rule, we are finalizing our proposal to make the EHR exception permanent by removing the sunset provision at § 411.357(w)(13).

We received the following comment and our response follows.

Comment: We received almost unanimous support to remove the sunset date in the EHR exception. Commenters asserted that the elimination of the sunset date would provide certainty regarding the availability of an exception to the physician self-referral law for ongoing donations of electronic health records items and services. Commenters also agreed with our statement in the proposed rule that the exception will remain necessary after 2021, given new entrants, aging electronic health records technology at existing practices, and emerging and improved technology. In contrast, one commenter suggested that, after 2021, the exception should only be available to rural providers and to physicians entering into solo practice in a health professional shortage area or medically underserved area. According to the commenter, making the current exception permanent could incentivize entities to reward high referring physicians with new electronic health records systems or updates.

Response: We are finalizing our proposal to make the EHR exception permanent by removing the sunset date. We note that, as finalized, the exception continues to require at § 411.357(w)(6) that neither the eligibility of a physician to receive items or services nor the amount or nature of the items or services may be determined in any manner that directly takes into account

the volume or value of the physician's referrals or other business generated between the parties. Given this requirement, as well as the other requirements of the exception, we do not believe that making the EHR exception permanent poses a risk of program or patient abuse.

d. Definitions

In the proposed rule, we proposed to modify the definitions of ''electronic health record'' and ''interoperable'' (84 FR 55824 through 55825). We adopted definitions for these terms in the 2006 EHR final rule based on contemporaneous terminology, the emerging standards for electronic health records, and other resources cited by commenters at that time. Our proposed modifications to these definitions were largely based on terms and provisions in the Cures Act that update or supersede terminology we used in the 2006 EHR final rule (84 FR 55824 through 55825). We discuss our specific proposals and our final policies and regulations pertaining to definitions of ''electronic health record'' and ''interoperable'' below in subsections (1) and (2), respectively.

(1) ''Electronic Health Record''

The term ''electronic health record'' is defined at § 411.351 as a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions. We proposed to revise this definition so that ''electronic health record'' would mean a repository that includes electronic health information that: (1) Is transmitted by or maintained in electronic media; and (2) relates to the past, present, or future health or condition of an individual or the provision of health care to an individual (84 FR 55824). We proposed the modifications to reflect the term ''electronic health information'' that is used throughout the Cures Act and that is central to the definition of interoperability at section 3000(9) of the PHSA and the information blocking provisions at section 3022 of the PHSA. We based our proposed modifications, in part, on ONC's proposed definition of ''electronic health information'' in the ONC NPRM (84 FR 7513), which reflects more modern terminology used to describe the type of information that is part of an electronic health record. We solicited comments on this updated definition (84 FR 55824).

After reviewing the comments on our proposed definition of ''electronic health record,'' we are not finalizing our proposal to modify the definition. Rather, we are retaining the current definition of ''electronic health record'' at § 411.351.

We received the following comments and our responses follow.

Comment: Several commenters expressed general support for our proposed revision to the definition of ''electronic health record,'' particularly to the extent that the definition would align with the definition included in the Cures Act. Some commenters supported our proposal to incorporate the term ''electronic health information,'' which ONC proposed to define in the ONC NPRM. According to one commenter, the broad definition of ''electronic health information'' in the ONC NPRM would ensure that data related to medical imaging, such as electronic orders and referrals for radiology services, would be subject to the information blocking provisions. The commenter suggested that, if ONC does not finalize a broad definition of ''electronic health information,'' CMS should retain the term ''consumer health status information'' in the definition of ''electronic health record.'' Another commenter maintained that, to further the agency's price transparency goals, CMS should explicitly define ''electronic health record'' to include electronic health information that relates to the past, present, or future payment for the provision of health care to an individual.

In contrast, several other commenters objected to the inclusion of the term ''electronic health information'' in the definition of ''electronic health record.'' Noting that, at the time we issued our proposed rule, ONC had not finalized its definition of ''electronic health information,'' these commenters maintained that the definition proposed by ONC is overly broad. For example, one commenter asserted that, under the proposed definition, a patient's computer or mobile telephone could be considered an electronic health record if the patient obtained a copy of his or her health record through electronic transmittal. Some commenters specifically stated that the proposed definition of ''electronic health record'' was too broad because, as proposed, it would have included financial information pertaining to payment for the provision of health care to an individual. Several commenters also made suggestions to limit the scope of ''electronic health information.''

Response: As stated in the proposed rule and reiterated above, our proposal to modify the definition of ''electronic health information'' was meant to update terminology that we adopted in the 2006 EHR final rule (84 FR 55824). We did not intend for our proposed modifications to the definition of ''electronic health record'' to make a substantive change to the scope of the exception at § 411.357(w). We agree with commenters that our proposed changes might have inadvertently introduced undesirable complexity. To remain true to our intent, we are not finalizing any of the proposed changes to the definition of ''electronic health record,'' and we are retaining the existing definition in our regulations. We also note that ONC published its final definition of ''electronic health information'' in the **Federal Register** on May 1, 2020, well after the comment period for our proposed rule closed on December 31, 2019, and the final definition of ''electronic health information'' (85 FR 25955) differs from the definition that ONC proposed (84 FR 7601). Among other things, as ONC explained in its final rule, the definition of ''electronic health information'' in ONC's final rule does not expressly include or exclude price information (85 FR 25804). Given that ONC's final definition differs from the definition in the ONC NPRM, which we cited in our proposed rule, and that ONC's final rule was published after the comment period for our proposed rule closed, we are concerned that the public may have not had sufficient information to comment on our proposal to incorporate the concept of ''electronic health information'' in the definition of ''electronic health record.'' Finally, although CMS remains committed to the price transparency initiative, at this time, we do not believe that modifying the definition of ''electronic health record'' with the resulting impact on the scope and requirements of the EHR exception is the best means to achieve this goal.

(2) ''Interoperable''

The term ''interoperable'' is currently defined at § 411.351 to mean able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purposes and meaning of the data are preserved and unaltered. This definition of ''interoperable'' was based on 44 U.S.C. 3601(6) (pertaining to the management and promotion of electronic Government services) and several comments we received in response to our 2005 rulemaking proposing exceptions for certain electronic prescribing and electronic health records arrangements (70 FR 59182) that

referenced emerging industry definitions and standards related to interoperability (71 FR 45155 through 45156).

In the proposed rule, we proposed to update the definition of ''interoperable'' to align with the statutory definition of ''interoperability'' added by the Cures Act to section 3000(9) of the PHSA (84 FR 55824 through 55825). Consistent with section 3000(9) of the PHSA, we proposed to define ''interoperable'' to mean: (i) Able to securely exchange data with and use data from other health information technology without special effort on the part of the user; (ii) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (iii) does not constitute information blocking as defined in section 3022 of the PHSA (84 FR 55824 through 55825). We stated that, should ONC finalize its proposals to implement section 3022 of the PHSA at 45 CFR part 171, and if we finalize our proposed definition of ''interoperable,'' we would incorporate the final ONC regulations into the definition of ''interoperable'' at § 411.351 by referencing 45 CFR part 171 instead of section 3022 of the PHSA (84 FR 55825).

We also noted in the proposed rule that the statutory definition of ''interoperability'' includes concepts similar to the existing definition of ''interoperable'' at § 411.351 (for example, the ability to securely exchange data across different systems or technology) (84 FR 55825). Two new concepts in the statutory definition were included in our proposed modification of the definition: (1) Interoperable means the ability to exchange electronic health information without special effort on the part of the user; and (2) interoperable expressly does not mean information blocking (Section 3000(9) of the PHSA; (42 U.S.C. 300jj(9)). We stated that, as a practical matter, we believe that these two concepts are not substantively different from the existing definition and only reflect an updated understanding of interoperability and related terminology, and solicited comments on a definition that would align the definition of ''interoperable'' at § 411.351 (for purposes of the physician self-referral law) with the statutory definition ''interoperability'' at 3000(9) of the PHSA (84 FR 55825).

As an alternative proposal, we considered revising our regulations to eliminate the term ''interoperable'' and instead define the term ''interoperability'' by reference to section 3000(9) of the PHSA and 45 CFR part 170 (if finalized) (84 FR 55825). In conjunction, we would revise the EHR exception to incorporate the term ''interoperability'' and remove the term ''interoperable.'' We sought comment regarding whether using terminology identical to the PHSA and ONC regulations would facilitate compliance with the requirements of the EHR exception and reduce any regulatory burden resulting from the differences in the agencies' varying terminology related to the singular concept of interoperability (84 FR 55825). We are not finalizing this alternative proposal.

After reviewing the comments on our proposals, we are revising the definition of ''interoperable,'' but omitting the provision related to information blocking and deleting the phrase ''without special effort on the part of the user'' from proposed subparagraph (1). Specifically, at revised § 411.351, ''interoperable'' means: (1) Able to securely exchange data with and use data from other health information technology; and (2) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law.

We received the following comments and our response follows.

Comment: We received general support for our effort to align the definition of ''interoperable'' with the statutory definition of ''interoperability'' in the Cures Act. However, citing uncertainty regarding the proposals in the ONC NPRM, one commenter requested that CMS not define ''interoperable'' with reference to ONC's proposed definition. The commenter also requested that CMS not replace the definition of ''interoperable'' with a definition of ''interoperability'' that cites ONC's proposed definition at 45 CFR 170.102. One commenter supported including a provision pertaining to information blocking in the definition, while several other commenters raised questions about the incorporation of information blocking in the definition of ''interoperable.'' For example, these commenters asked when the test for interoperability occurs and whether a prior donation of electronic health records items or services would cease to satisfy the requirements of the EHR exception if there was a finding of information blocking sometime after the donation. One commenter asked for further clarification of the phrase ''without special effort on the part of the user.''

Response: As we explain above in the discussion of our proposal to include the concept of ''information blocking'' in the exception at § 411.357(w)(3), we believe that newer and separate authorities are better suited than the EHR exception to deter information blocking and hold individuals and entities that engage in information blocking appropriately accountable. We are concerned that, if we include the phrase ''does not constitute information blocking'' in the definition of ''interoperable'' at § 411.351, then § 411.357(w)(2), which requires that the donated software is interoperable, could be interpreted to prohibit parties from engaging in practices that constitute ''information blocking'' but that might not be prohibited under ONC rules. Therefore, we are not including the phrase ''does not constitute information blocking'' in the definition of ''interoperable'' at § 411.351.

With respect to the phrase ''without special effort on the part of the user,'' we note that, the phrase is used in the definition of ''interoperability'' at section 4003(a)(2) of the Cures Act and the partial phrase ''without special effort'' is used in the conditions of certification at section 4002(a) of the Cures Act. As explained above, although software certified by ONC is deemed to be interoperable for purposes of the physician self-referral law, certification is not required for compliance with § 411.357(w)(2). To avoid any implication that we are incorporating a certification requirement into the definition of ''interoperable'' at § 411.351, we are removing the phrase ''without special effort on the part of the user'' from the definition.

e. Additional Proposals and Considerations

(1) 15 Percent Recipient Contribution (§ 411.357(w)(4))

In the 2006 EHR final rule, we agreed with a number of commenters that suggested that cost sharing is an appropriate method to address some of the program integrity risks inherent in unlimited donations of electronic health records items and services (71 FR 45160 through 45161). Accordingly, we incorporated a requirement at § 411.357(w)(4) that, before the receipt of the items or services, the physician pays 15 percent of the donor's cost of the items or services. We stated our belief that the 15 percent cost sharing requirement is high enough to encourage prudent and robust electronic health records arrangements without imposing a prohibitive financial burden on recipients. Moreover, we stated that this approach requires recipients to contribute toward the benefits they may experience from the adoption of interoperable electronic health records software (for example, a decrease in

practice expenses or access to incentive payments related to the adoption of electronic health records technology).

We received a number of comments in response to the CMS RFI, and OIG received similar comments in response to its request for information, asserting that the 15 percent contribution requirement of the EHR exception has been burdensome to some recipients and acts as a barrier to adoption of electronic health records. Some commenters on the requests for information asserted that this burden may be particularly acute for small and rural practices that cannot afford the contribution. Other suggested that applying the 15 percent contribution requirement to upgrades and updates to electronic health records software is restrictive and cumbersome and similarly acts as a barrier.

In the proposed rule, we considered and solicited comments on two alternatives to the existing requirement at § 411.357(w)(4) as outlined below, but did not propose specific regulation text along with the proposals (85 FR 55825). First, we considered eliminating the contribution requirement or reducing the percentage that small or rural physician organizations would be required to contribute. In conjunction with this proposal, we solicited comments on how we should define ''small or rural physician organization.'' We also solicited comments on whether ''rural physician organization'' should be defined as a physician organization located in a rural area, as that term is defined at § 411.351, or defined in line with the definition of ''rural provider'' at § 411.356(c)(1). We also solicited comments on other subsets of potential physician recipients for which the 15 percent contribution is a particular burden. As an alternative, we proposed to reduce or eliminate the 15 percent contribution requirement in the EHR exception for all physician recipients. We solicited comments regarding the impact this might have on the use and adoption of electronic health records technology, as well as any attendant program integrity concerns. We solicited comments requesting specific examples of any prohibitive costs associated with the 15 percent contribution requirement, both for the initial donation of electronic health records items and services, and subsequent upgrades and updates to previously donated electronic health records items and services.

Finally, in the proposed rule, we also considered modifying or eliminating the contribution requirement for updates to previously donated electronic health records software or services, regardless of whether we determined to retain the 15 percent contribution requirement or reduce that contribution requirement for some or all physician recipients (85 FR 55825). We solicited comments on this approach as well as what such a modification should entail. For example, we considered requiring a contribution for the initial donation only, as well as any new electronic health records software modules, but not requiring a contribution for any update of the software already donated. We solicited comments on these alternatives, or another similar alternative that would still involve some contribution but could reduce the uncertainty and administrative burden associated with assessing a contribution for each update of the software already donated.

After reviewing the comments, we are retaining the 15 percent cost contribution requirement for all physician recipients. However, in response to comments, we are revising § 411.357(w)(4) as it pertains to the timing of payments. Under revised § 411.357(w)(4)(i), a physician must pay the required cost contribution amount before receiving an initial donation of electronic health records items and services or a donation of replacement items and services. However, with respect to items or services donated after the initial donation or the replacement donation, final § 411.357(w)(4)(ii) requires that the cost contribution amount must be paid at reasonable intervals. Specifically, as finalized, § 411.357(w)(4)(i) and (ii) require that: (i) Before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services; and (ii) except as provided in subparagraph (i), with respect to items or services received from the donor after the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services at reasonable intervals. We are not modifying § 411.357(w)(4)(iii), which requires that the donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

We received the following comments and our responses follow.

Comment: A large number of commenters recommended that we remove the 15 percent contribution requirement for all donations and for all recipients or, in the alternative, reduce the contribution requirement to 5 percent of the donor's cost for the items and services. Commenters provided a number of reasons in support of their request to remove the contribution requirement. One commenter noted that the contribution requirement may pose a barrier to physicians who have not yet adopted electronic health records software, and added that, even if the contribution requirement is eliminated, physicians would still be required to bear other costs related to electronic health records implementation, such as hardware, staff time, and other resources. A few commenters stated that the contribution requirement may be an unreasonable constraint on how health systems and hospitals finance the needed infrastructure to implement new value-based payment models and promote coordination of care. One of these commenters asserted that a common electronic health records system across a network of hospitals and physicians fosters a higher degree of integrated care, better and more timely access to services through coordinated systems, alignment of quality standards across all participating providers, and a more structured approach to optimizing utilization, thus contributing to higher quality and more affordable care. However, according to the commenter, small and independent practices typically cannot afford the electronic health records systems used by a larger health care system, even at a discount, which leads to a network of disjointed care and service offerings. Other commenters cited the added burden involved in setting the contribution amount in writing and the necessary, ongoing monitoring to ensure compliance. One of these commenters also highlighted that eliminating the requirement would align the EHR exception with the proposed cybersecurity exception at § 411.357(bb), which does not include a contribution requirement. Several commenters that supported eliminating the contribution requirement as a requirement of the EHR exception suggested that CMS should still allow the donor to require a contribution. One of the commenters suggested that any contribution requirement should be left up to market forces and negotiation between the parties, and another suggested that the contribution amount should be at the discretion of the donor, as long as the donor consistently and fairly applies its policy to all recipients.

In contrast, some commenters raised concerns about eliminating the contribution requirement. One of these commenters maintained that physician adoption and use of an electronic health

records system is improved when physicians have a certain level of buy-in and share in the financial cost. Similarly, other commenters suggested that 15 percent represents a fair contribution amount, the contribution requirement serves as a reasonable safeguard to reduce wasteful spending, and it is important for recipients to have a stake in the purchased technology.

Response: After careful consideration, we continue to believe that the contribution requirement is an important safeguard to protect against program or patient abuse. When recipients of valuable remuneration have some responsibility to contribute to the cost of the items or services, they are more likely to make economically prudent decisions and accept only items and services that they need. As described below, we are revising the requirement at § 411.357(w)(4) to increase flexibility in connection with administering the contribution requirement. We note that, depending on the facts and circumstances, donations of electronic health records items and services may be permissible under the new exceptions for arrangements that facilitate value-based health care delivery and payment at § 411.357(aa). There is no requirement in the exceptions at final § 411.357(aa)(1), (2), or (3) that recipients of the electronic health records items or services contribute to the donor's cost for the items or services.

Comment: Many commenters suggested that, if CMS determines not to eliminate the 15 percent contribution requirement for all physician recipients, it should eliminate the requirement for at least a subset of recipients, such as small, rural, or tribal physician practices; free and charitable clinics; physicians with demonstrable financial need; or physician practices located in underserved areas, including urban practices serving low-income Medicaid populations. Several commenters stated that the contribution requirement presents a significant financial barrier for these physician practices that could negatively impact patient care, and one commenter maintained that the contribution requirement ''prices out'' physicians in small, rural, or underserved practices, while another stated that the 15 percent contribution requirement is ''too steep'' for many small practices. Another commenter believed that the contribution requirement could be lowered for small and rural physician organizations, provided that the donor is still permitted to decide the cost sharing amount required.

Some commenters that favored eliminating the contribution requirement for a subset of physician practices, such as small or rural practices and practices in underserved areas, provided a variety of definitions for small, rural, and underserved practices, including definitions based on the Quality Payment Program; the anti-kickback statute safe harbor for local transportation; the North American Industry Classification System for small businesses; and the Secretary's designation of medically underserved areas and primary health care geographic health professional shortage areas. Some commenters expressed concern that different contribution requirements for different sets of physician practices may be difficult to administer and increase burden and, therefore, supported removing the contribution requirement for all physicians.

Response: As we explained in response to the immediately previous comment, we are retaining the 15 percent contribution requirement for all recipients seeking to protect donations of electronic health records items and services under the EHR exception. We agree with the commenters that identified the challenges of defining subgroups of entities to exempt from this requirement. Even if we were to adopt definitions for the categories of physician recipients who would be exempted from the contribution requirement—whether by adopting definitions existing in other regulations or definitions suggested by commenters—we are cognizant that qualification under a designation can change over time (for example, a physician practice may qualify as a ''small practice'' at some points in time but not at others, depending on staffing changes), resulting in significant compliance challenges when such a change occurs. In addition, the program integrity risks associated with donations of electronic health records items and services apply regardless of the geography or size of the donation recipient. Again, we note that, to the extent that the donation of electronic health records items and services is made under a value-based arrangement (as defined at § 411.351), no recipient contribution is required, provided that the arrangement satisfies all the requirements of an applicable exception at final § 411.357(aa).

Comment: A number of commenters asked that, if CMS retains a contribution requirement on the initial donation of electronic health records items and services, the contribution requirement be eliminated for updates to the original donation. Commenters noted that updates may ensure that an electronic health records donation continues to function as needed and to meet current Federal standards for data exchange. One commenter stated that it is not uncommon for a donor's electronic health records system to be linked to a recipient's system, and the two systems must be in sync if they share an ''instance'' of electronic health records software. According to the commenter, updates to the donor's system must also be passed on to the recipient's electronic health records system, even if the recipient does not need, want, or use the updates. The commenter contended that, with respect to such updates, the 15 percent cost contribution requirement functions as a tax that damages the financial stability of small practices. Another commenter recommended that CMS consider retaining a contribution requirement only for the provision of replacement software while eliminating it for the initial donation and any updates to that initially donated system.

Response: As explained in response to comments above, we are retaining the contribution requirement for all electronic health records donations, including updates. We recognize that updates are crucial for the continuing functionality of an electronic health records system; however, we do not believe that it is appropriate to retain a contribution requirement for certain donations and eliminate it for others. We are concerned about gaming under such a regulatory scheme; for example, the parties could structure the ''initial'' donation to consist of a functionality with a low cost, and consequently, a small required contribution, with the most valuable functionality provided later as an ''update'' with no required contribution. For this reason, we believe that a cost contribution requirement is appropriate for all donations, including updates. However, as explained in our response to comments below, for updates to previously donated electronic health records items or services, we are no longer requiring that the contribution be made before the receipt of items and services.

Comment: Some commenters addressed other aspects of the contribution requirement at § 411.357(w)(4). For example, one commenter expressed concern about the requirement that the physician recipient must pay the required contribution before the items or services are received. This commenter noted that recipients may unintentionally fail to satisfy this requirement due to inadvertent late payments and requested that CMS add

a remedy period for mistakes to be corrected. Another commenter recommended eliminating the requirement that the physician make the required contribution payment prior to the receipt of services and recommended instead that CMS require that the parties have in place a commercially reasonable collections process.

Response: We are aware that assessing a contribution for each update could create compliance challenges and increase administrative burden. We recognize that updates may need to take place quickly to remedy security or other problems in an electronic health records system, and we understand the commenter's concern about inadvertent late payments under such circumstances. We do not believe that it would pose a risk of program or patient abuse to permit a physician to pay required contribution amounts after receipt of an update, provided that payments are made at reasonable intervals. In contrast, with respect to an initial donation of items or services, or a donation that will replace existing items or services, we believe that parties can effectively plan the donation, with all expenses known in advance. Thus, there does not exist the same administrative burden or potential for inadvertent late payments that may exist with the timing of payments for periodic updates. In light of this, we are modifying the requirement at § 411.357(w)(4) to permit payments of the cost contribution for items and services received after the initial donation or replacement donation at reasonable intervals, rather than in advance of the receipt of the items and services. Of course, parties remain free to require advance payments under their electronic health records donation arrangement. The regulation continues to require that the physician recipient pays the cost contribution amount for the initial donation of items or services or the donation of replacement items or services before the items or services are received. We note that the EHR exception does not require a specific billing method, but the contribution amounts must actually be paid by the physician and be paid at reasonable intervals. A donor could choose to bill a recipient separately for each update or could bill the recipient monthly or quarterly to combine the contribution payments for all updates during a select period of time. Given the modifications to § 411.357(w)(4) that we are finalizing here, we do not believe that it is necessary to add a remedy period for mistakes to be corrected, as suggested by the commenter.

Comment: One commenter recommended that we not require a 15 percent contribution for cybersecurity donations under the EHR exception. The commenter noted that some organizations will only permit practices to use their electronic health records systems if the practice has certain cybersecurity protections, and thus the commenter suggested that the party requiring the cybersecurity protection should pay any costs associated with it.

Response: We are not finalizing separate requirements for different types of donations within this exception. If a party seeks to protect a donation of cybersecurity software or services under the EHR exception, then a contribution toward the cost of the items and services is required. However, as explained in our response to comments above, a physician need not pay the 15 percent cost contribution for cybersecurity technology and services donated in conjunction with electronic health records items and services if the donation of the cybersecurity technology or services satisfies all the requirements of final § 411.357(bb).

Comment: One commenter stated that donations of items and services under the EHR exception are typically made to a physician practice, as opposed to an individual physician. However, the cost contribution requirement at § 411.357(w)(4) requires the physician to pay 15 percent of the donor's cost. The commenter stated that, given this language, it is unclear whether individual physicians or the physician practice must pay the cost contribution. The commenter requested that CMS clarify that donations may be made to a physician organization as the sole contracting party and as the sole contributor to the donor's cost.

Response: Because the physician self-referral law is implicated when a financial relationship exists between a physician (or an immediate family member of a physician) and an entity, the exception for electronic health records items or services at § 411.357(w) is structured to apply to remuneration from an entity to a physician. The commenter correctly notes that the cost contribution requirement at § 411.357(w)(4) requires the physician to pay 15 percent of the donor's cost. The required contribution amount may be paid by the physician or on behalf of the physician by his or her physician organization.

With respect to donations to physicians in a physician organization consisting of more than one physician, we note the following. We acknowledge, as the commenter stated, that donations of items and services under the EHR exception are often made to a physician organization, as opposed to an individual physician. When an arrangement for the donation of electronic health records items and services is between the donor entity and a physician organization, under our regulation at § 411.354(c)(1), each physician who stands in the shoes of the physician organization is deemed to have the same compensation arrangement as the physician organization. Thus, the donation of the electronic health records items and services to the physician organization is deemed to establish a direct compensation arrangement between each physician who stands in the shoes of the physician organization and the entity donating the electronic health records items and services. Each of those ''deemed direct'' compensation arrangements must satisfy the requirements of an applicable exception in order to avoid the physician self-referral law's referral and billing prohibitions. However, unlike many other forms of nonmonetary compensation, the cost of electronic health records items and services is oftentimes capable of being allocated on a per-user basis. Thus, when a donor entity divides the cost of electronic health records items and services among physician recipients in an appropriate manner (for example, per capita or by estimated usage based on their portions of the physician organization's patient universe or visits), the donation of electronic health records items and services to the physicians in a physician organization is properly viewed as a direct compensation arrangement between the donor entity and each recipient physician, rather than ''deemed direct'' compensation arrangements that result from applying the ''stand in the shoes'' provisions at § 411.354(c)(1). In such circumstances, each physician recipient would be required to contribute 15 percent of the cost of the electronic health records items and services specifically allocated to him or her, rather than the cost of the entire suite of electronic health records items and services provided to the physician organization as a whole. The required contribution amount may be paid by each individual physician or on behalf of the physicians by the physician organization.

To illustrate, assume that a donor entity wishes to provide licenses for the physicians in a physician organization to access and utilize electronic health records items and services, and the cost

of the license is $100,000 per year for 25 licenses. The donor entity may divide the cost of the 25 licenses among the potential licensees, and allocate $4,000 to each physician recipient. Thus, if the donor entity provided 10 licenses to a physician organization, it could allocate $4,000 per physician recipient, establishing a direct compensation arrangement with each physician recipient. In these circumstances, each physician recipient must pay 15 percent (or $600) of the cost of the license before receipt of the license in order to satisfy the requirement at § 411.357(w)(4). In contrast, assume that a donor entity provides information technology and training services that are not readily or appropriately divisible by any particular number of licensees or users. If the cost of the items and services provided to a physician organization cannot readily and appropriately be divided among the individual physician recipients of the items and services, under the regulation at § 411.354(c)(1), the entirety of the items and services are deemed to be provided to each physician who stands in the shoes of the physician organization.

(2) Equivalent Items and Services (§ 411.357(w)(8))

In the 2013 EHR final rule, we highlighted a commenter's assertion that the prohibition on donating equivalent items or services currently included in the exception at § 411.357(w)(8) locks physician practices into a vendor, even if they are dissatisfied with the donated items or services, because the recipient must choose between paying the full amount for a new electronic health records system and continuing to pay 15 percent of the cost of the substandard system (78 FR 78766). That commenter asserted that the cost differential between these two options is high enough to effectively locks physician practices into electronic health records technology vendors. In the 2013 EHR final rule, we responded that we continued to believe that items and services are not necessary if the recipient already possesses the equivalent items or services. We noted that providing equivalent items and services confers independent value on the physician recipient and stated our expectation that physicians would not select or continue to use a substandard system if it posed a threat to patient safety.

We appreciate that advancements in electronic health records technology are continuous and rapid. According to commenters on the CMS RFI and OIG's request for information, in some situations replacement electronic health records items or services are appropriate but prohibitively expensive. In the proposed rule, we proposed to permit donations of replacement electronic health records items or services under the EHR exception (84 FR 55826). We specifically sought comment as to the types of situations in which the donation of replacement items and services would be appropriate. We further solicited comment as to how we might safeguard against donors inappropriately offering, or physician recipients inappropriately soliciting, unnecessary items and services instead of upgrading their existing technology for appropriate reasons. Based on our review of the comments, we are finalizing our proposal to permit donations of replacement items and services by removing the requirement at § 411.357(w)(8) that the donor does not have actual knowledge of, or and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor, which we have historically interpreted as a prohibition on the donation of replacement technology.

We received the following comment and our response follows.

Comment: Commenters broadly supported removing the requirement at § 411.357(w)(8) that effectively prohibits a donor from donating replacement items and services under the EHR exception. Commenters provided a number of reasons for their support of the elimination of this requirement, highlighting that, because they cannot afford the full cost to replace their electronic health records systems, some physician practices may work with an electronic health records system that no longer meets their needs, is outdated, or is otherwise substandard. Similar to the commenter on the 2013 EHR proposed rule, a few commenters maintained that the prohibition on replacement items and services locks a physician recipient into a particular vendor, even if the physician is not satisfied with its current electronic health records system, because the cost for a new system is significantly higher than continued payment of a 15 percent contribution for updates to the physician's current electronic health records software. One commenter stated that one of its clinically integrated networks operates with more than two dozen electronic health records systems. The commenter explained that, although it has developed a system to aggregate all patient information, the diverse electronic health records systems made the solution less than optimal. The commenter explained that, if the restriction on donations of replacement items and services were lifted, it could achieve greater efficiency and care coordination by migrating the network to one unified electronic health records system. A different commenter recommended that CMS eliminate the requirement at § 411.357(w)(8) but require a documented rationale for the need of replacement items and services, while another commenter suggested that donations of replacement items and services should be permitted only if the recipient contributes 15 percent of the cost of the replacement software and services and demonstrates in writing, accompanied by documentation from an objective third party, that the recipient's current electronic health records system is substandard such that it poses a threat to patient safety. Similarly, one commenter suggested that donations of replacement software should only be permitted if the software that the physician is currently using no longer meets certification criteria.

Response: We are removing the requirement at § 411.357(w)(8) from the EHR exception. We recognize that there may be valid business or clinical reasons for a physician recipient to replace an entire electronic health records system rather than update existing items and services, even if the existing software meets current certification criteria and does not pose a threat to patient safety. Under the revised EHR exception, replacement items and services are treated the same as a new donation and arrangements for the donation of replacement electronic health records items and services would need to satisfy all the requirements of the exception to avoid the referral and billing prohibitions of the physician self-referral law. For example, under § 411.357(w)(4)(i), a recipient of replacement items and services would be required to pay at least 15 percent of the donor's cost for the items and services before receiving them. We believe that treating a donation of replacement items and services the same as a new donation strikes an appropriate balance between making necessary replacements financially feasible for recipients and maintaining safeguards to protect against program or patient abuse, such as recipients inappropriately soliciting or accepting unnecessary electronic health records items and services.

12. Exception for Assistance to Compensate a Nonphysician Practitioner (§ 411.357(x))

Section 1877(e)(5) of the Act sets forth an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital to be a member of the hospital's medical staff, subject to certain requirements. This exception is codified in our regulations at § 411.357(e). In Phase III, we declined one commenter's request to expand § 411.357(e) to cover the recruitment of nonphysician practitioners (NPPs) into a hospital's service area, including into an existing physician practice, stating that the exception for physician recruitment at § 411.357(e) applies only to payments made directly (or, in some circumstances, passed through) to a recruited physician (72 FR 51049). Recruitment payments made by a hospital directly to an NPP would not implicate the physician self-referral law, unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician. We further stated that payments made by a hospital to subsidize a physician practice's costs of recruiting and employing NPPs would create a compensation arrangement between the hospital and the physician practice for which no exception would apply, and that these kinds of subsidy arrangements pose a substantial risk of fraud and abuse. Following the publication of Phase III, we reconsidered our position. There have been significant changes in our health care delivery and payment systems, as well as projected shortages in the primary care workforce. To address this changed landscape, in the CY 2016 PFS final rule, we finalized a limited exception at § 411.357(x) for hospitals, FQHCs, and rural health clinics (RHCs) to provide remuneration to a physician to assist with the employment of (or other compensation arrangement with) an NPP (80 FR 71301 through 71311).

The exception at § 411.357(x) applies to remuneration provided by a hospital to a physician to compensate an NPP to provide patient care services. As we noted in the proposed rule, we have received several inquiries regarding the meaning of the term ''patient care services'' as it relates to an NPP. The inquiries generally concentrate on the requirement at § 411.357(x)(1)(v)(B) that the NPP has not, within 1 year of the commencement of his or her compensation arrangement with the physician, been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital. Often, prior to becoming an NPP, an individual may have been a registered nurse (or some other health care professional) and may have provided services to patients that are similar to the services provided by an NPP. For purposes of the exception at § 411.357(x), the question presented by stakeholders is whether the services provided by the individual before the individual became an NPP constitute ''patient care services.''

As we explained in the proposed rule, the definition of ''patient care services'' found at § 411.351 relates to tasks performed by a physician only (84 FR 55826). To clarify the meaning of ''patient care services'' for purposes of the exception for assistance to compensate an NPP, we proposed to revise § 411.357(x) to change the references to ''patient care services'' to ''NPP patient care services'' and include a definition of the term ''NPP patient care services'' in the exception at § 411.357(x)(4)(i). We proposed to define ''NPP patient care services'' to mean direct patient care services furnished by an NPP that address the medical needs of specific patients or any task performed by an NPP that promotes the care of patients of the physician or physician organization with which the NPP has a compensation arrangement. Under the definition of ''NPP patient care services,'' services provided by an individual who is not an NPP (as the term is defined at § 411.357(x)(3)) at the time the services are provided, are not NPP patient care services for purposes of § 411.357(x). Thus, if an individual worked in the geographic area served by the hospital providing the assistance (for example, as a registered nurse) for some period immediately prior to the commencement of his or her compensation arrangement with the physician or physician organization in whose shoes the physician stands, but had not worked as an NPP in that area during that period, the exception at § 411.357(x) would be available to protect remuneration from the hospital to the physician to compensate the NPP to provide NPP patient care services, provided that all the requirements of the exception are satisfied. In this example, the registered nursing services would not be considered NPP patient care services when determining whether the arrangement satisfies the 1-year restriction at § 411.357(x)(1)(v) (84 FR 55826).

We also proposed conforming changes to the term ''referral'' as defined at § 411.357(x)(4) for purposes of the exception. Specifically, we proposed to revise § 411.357(x) to change references to ''referral'' when describing the actions of an NPP to ''NPP referral'' and revise § 411.357(x)(4) accordingly. We stated, and affirm here, that it is unnecessary to have a general definition of ''referral'' at § 411.351 that is applicable throughout our regulations and a different definition of the same term (''referral'') that applies only for purposes of the exception at § 411.357(x). We did not propose substantive changes to the definition itself; however, we proposed to move the definition to § 411.357(x)(4)(ii) in order to accommodate the inclusion of the related definition of ''NPP patient care services'' within section § 411.357(x)(4) (84 FR 55826).

We also proposed a related change to § 411.357(x)(1)(v)(A). As drafted, § 411.357(x)(1)(v)(A) requires the NPP to not have practiced in the geographical area served by the hospital within 1 year of the commencement of the compensation arrangement with the physician. According to stakeholders that requested guidance on the scope of the exception, the word ''practiced'' may be interpreted to include the provision of NPP patient care services (as we proposed to define the term here) and other services, for example, services provided by a health care professional who is not an NPP at the time the services are furnished. To resolve any potential stakeholder confusion, we proposed to replace the term ''practiced'' with ''furnished NPP patient care services.'' Under the proposal, a hospital would not run afoul of § 411.357(x)(1)(v)(A) if the hospital provided remuneration to a physician to compensate an NPP, and the individual receiving compensation from the physician furnished services in the hospital's geographic service area within 1 year of the commencement of his or her compensation arrangement with the physician, provided that the services furnished by the individual during the 1-year period were not NPP patient care services, as we proposed to define the term at § 411.357(x)(4)(i) (84 FR 55826 through 55827).

In addition to the inquiries related to the meaning of the terms ''patient care services'' and ''practice,'' we noted our awareness of stakeholder uncertainty regarding the timing of arrangements that may be permissible under § 411.357(x). Specifically, stakeholders have inquired whether an NPP must begin his or her compensation arrangement with the physician (or physician organization in whose shoes the physician stands) on or after the

commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician, noting that the exception includes no explicit prohibition on an entity providing assistance to a physician to reimburse the physician for the compensation, signing bonus, or benefits paid to an NPP already employed or contracted by the physician prior to the date of the commencement of the physician's compensation arrangement with the hospital, FQHC, or RHC. As we stated when finalizing the exception at § 411.357(x), our underlying goal is to increase access to needed care (80 FR 71309). Permitting a hospital, FQHC, or RHC to simply reimburse a physician for overhead costs of current employees or contractors already serving patients in the geographic area served by the hospital, FQHC, or RHC does not support this goal. Nonetheless, as stakeholders pointed out, there is no express requirement regarding the timing of the compensation arrangement between the NPP and the physician (or physician organization in whose shoes the physician stands) in § 411.357(x). To ensure that compensation arrangements protected under the exception do not pose a risk of program or patient abuse, we proposed to amend § 411.357(x)(1)(i) to expressly require that the compensation arrangement between the hospital, FQHC, or RHC and the physician commences before the physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) enters into the compensation arrangement with the NPP (84 FR 55827). Put another way, the compensation arrangement between the NPP and the physician (or physician organization in whose shoes the physician stands) must commence on or after the commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician.

We received a number of comments in support of our clarifying proposals. Although we received a few comments addressing issues outside the scope of our proposals, we did not receive any comments objecting to our proposals or suggesting alternatives for clarifying the requirements of the exception for assistance to compensate a nonphysician practitioner. We are finalizing the proposed revisions to § 411.357(x) without modification.

We received the following comments and our responses follow.

Comment: Most commenters that commented on our proposal supported the proposed modifications to clarify the terminology used in the exception and that the exception cannot be used to reimburse physicians for compensation, signing bonus, and benefits expenses related to NPPs who were employed or contracted before the commencement of the compensation arrangement between the hospital and the physician.

Response: As discussed above, we are finalizing our clarifying revisions in the exception for assistance to compensate a nonphysician practitioner at § 411.357(x). We believe that the revisions finalized here will provide the clarity sought by stakeholders prior to the proposed rule.

Comment: Two commenters requested that CMS revise the exception at § 411.357(x) to remove any limits on the practice specialties of nonphysician practitioners for whom physicians may receive assistance. One of the commenters asserted that surgery, neurology, urology, and many other specialty services are areas of acute need for many communities. The commenter also recommended that we not limit the medical specialties of physicians who may receive assistance under the exception to physicians who provide ''primary care services or mental health services.'' The other commenter asserted that, although most nurse practitioners provide primary care or behavioral health services, nurse practitioners practice in nearly all practice specialties, and these medical practices are also in need of nurse practitioners, particularly in rural and underserved communities. This commenter suggested that CMS align the exception for assistance to compensate a nonphysician practitioner with the exception for physician recruitment, noting that the former exception is limited to nonphysician practitioners who, for the most part, provide primary care or behavioral health services, while no similar restriction applies to physician recruitment.

Response: The exception for assistance to compensate a nonphysician practitioner was proposed in the CY 2016 PFS proposed rule (80 FR 41686) and finalized in the CY 2016 PFS final rule (80 FR 70866). In the CY 2016 PFS proposed rule, we stated that our goal in proposing (and ultimately finalizing) the exception was to promote the expansion of access to primary care services, but sought comment regarding whether there was a compelling need to expand the scope of the exception to nonphysician practitioners who provide services that are not considered primary care services (80 FR 41911). In response, commenters requested that we broaden the scope of the exception. Commenters that suggested an expansion to mental health services provided convincing evidence of the compelling need for access to mental health care services throughout the country (80 FR 71306). However, commenters that requested the expansion of the exception to any other specialty services provided no documentation or other evidence of the compelling need for such an expansion (80 FR 71306 through 71307).

We did not propose to expand the scope of the exception for assistance to compensate a nonphysician practitioner in the proposed rule, and make no attempt to finalize such a regulatory modification in this final rule. However, we note that the commenters that made the requests for expansion of the scope of the exception, like those that commented on the CY 2016 PFS proposed rule, failed to provide any documentation or other evidence of the compelling need for such an expansion at this time. With respect to the commenter that suggested the exception for assistance to compensate a nonphysician practitioner at § 411.357(x) should be aligned with the exception for physician recruitment at § 411.357(e), we note that the exception for physician recruitment is statutory and covers only remuneration from a hospital to a physician to induce the physician to relocate his or her medical practice to the geographic area served by the hospital to become a member of the hospital's medical staff. In contrast, the underlying purpose of the exception to assist a physician to compensate a nonphysician practitioner is to promote expansion of access to primary care and mental health care services. There is no reason for the two exceptions to have identical requirements and scope.

13. Updating and Eliminating Out-of-Date References

a. Medicare+Choice (§ 411.355(c)(5))

Section 1877(b)(3) of the Act and § 411.355(c) of the physician self-referral regulations set forth exceptions for designated health services furnished by various organizations to enrollees of certain prepaid health plans. When the Medicare+Choice program was established in the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA), the Congress failed to update section 1877(b)(3) of the Act to except the designated health services furnished under Medicare+Choice coordinated care plans. Based on our belief that this was an oversight, in the June 26, 1998 interim final rule with comment period (Medicare Program; Establishment of the Medicare+Choice Program (63 FR 34968)), we revised § 411.355(c) to

accommodate the creation of the Medicare+Choice program and, relying on the Secretary's authority to create new exceptions under section 1877(b)(4) of the Act, we included Medicare+Choice coordinated care plans in § 411.355(c)(5) of our regulations (63 FR 35003 through 35004). (We declined to include Medicare+Choice medical savings account plans and Medicare+Choice private FFS plans due to the risk of patient abuse related to financial liability for premiums and cost sharing, which were not limited by the BBA.) We included Medicare+Choice coordinated care plans at § 411.355(c)(5), in part, to avoid contradiction with the BBA's establishment of provider-sponsored organization (PSO) plans as coordinated care plans. PSOs are defined in the BBA as entities that must be organized and operated by a provider (which may be a physician) or a group of affiliated health care providers (which may include physicians). The BBA requires that the providers have at least a majority financial interest in the entity and share a substantial financial risk for the provision of items and services. If such ownership was not excepted, the physician owners of PSOs would not be permitted to refer enrollees for designated health services furnished by the coordinated care plan (or its contractors and subcontractors). Subsequently, in 1999, the Congress amended section 1877(b)(3) of the Act to create a similar statutory exception for Medicare+Choice at section 1877(b)(3)(E) of the Act (Pub. L. 106–113).

Section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003) (MMA) renamed the Medicare+Choice program as the Medicare Advantage program and provided that any statutory reference to ''Medicare+Choice'' was deemed to be a reference to the Medicare Advantage program. In reviewing our regulations for out-of-date references, including references to Medicare+Choice, as part of this rulemaking, it came to our attention that the language of § 411.355(c)(5) may be inconsistent with other program regulations. Current § 411.355(c)(5) excepts designated health services furnished by an organization (or its subcontractors) to enrollees of a coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and Part 422 of Title 42, Chapter IV of the Code of Federal Regulations. For consistency with the MMA directive and to ensure the accuracy of our regulations, we proposed to revise § 411.355(c)(5) to more accurately reference Medicare Advantage plans. Under this proposal, § 411.355(c)(5) would reference designated health services furnished by an organization (or its contractors or subcontractors) to enrollees of a coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter. This proposal does not represent a change in our policy.

The Medicare Advantage program varies from the Medicare+Choice program in ways other than its name and has matured in the years since passage of the MMA. More than 20 years have passed since we determined to protect designated health services furnished to enrollees of coordinated care plans and exclude medical savings account plans and private FFS plans from the scope of § 411.355(c)(5). In light of this, we sought comments regarding whether § 411.355(c)(5) is broad enough to protect designated health services furnished to enrollees in the full range of Medicare Advantage plans that exist today and that do not pose a risk of program or patient abuse. Specifically, we were interested in commenters' views on which, if any, other Medicare Advantage plans we should include within the scope of § 411.355(c)(5).

We received the following comment and our response follows.

Comment: Multiple commenters supported the proposed updates and elimination of references to ''Medicare+Choice.'' We did not receive any comments opposing these changes.

Response: We are finalizing the changes as proposed.

b. Website

We proposed to modernize the regulatory text by changing ''Web site'' to ''website'' throughout the physician self-referral regulations to conform to the spelling of the term in the Government Publishing Office's Style Manual and other current style guides.

After reviewing the comments, we are finalizing our proposal to change ''Web site'' to ''website'' wherever the term appears in our regulations.

We received the following comment and our response follows.

Comment: Multiple commenters supported the proposed updates and elimination of references to ''Web site.'' We did not receive any comments opposing these changes.

Response: We are finalizing the changes as proposed.

E. Providing Flexibility for Nonabusive Business Practices

1. Limited Remuneration to a Physician (§ 411.357(z))

In the 1998 proposed rule, we proposed an exception for *de minimis* compensation in the form of noncash items or services (63 FR 1699). In Phase I, using the Secretary's authority at section 1877(b)(4) of the Act, we finalized the proposal at § 411.357(k) and changed the name of the exception to nonmonetary compensation, noting that, although free or discounted items and services such as free samples of certain drugs, chemicals from a laboratory, or free coffee mugs or note pads from a hospital fall within the definition of ''compensation arrangement,'' we believe that such compensation is unlikely to cause overutilization, if held within reasonable limits (66 FR 920). The exception for nonmonetary compensation at § 411.357(k) permits an entity to provide compensation to a physician in the form of items or services (other than cash or cash equivalents) up to an aggregate amount of $300 per calendar year, adjusted annually for inflation and currently $423 per calendar year, provided that the compensation is not solicited by the physician and is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. The exception does not require that the physician provide anything to the entity in return for the nonmonetary compensation, nor does it require that the arrangement is set forth in writing and signed by the parties.

We also recognized in Phase I that many of the incidental benefits that hospitals provide to medical staff members do not qualify for the exception at § 411.357(c) for *bona fide* employment relationships because most members of a hospital's medical staff are not hospital employees, nor would they qualify for the exception at § 411.357(l) for fair market value compensation because, to the extent that the medical staff membership is the only relationship between the hospital and the physician, there is no written agreement between the parties to which these incidental benefits could be added. We acknowledged that many medical staff incidental benefits are customary industry practices that are intended to benefit the hospital and its

patients; for example, free computer and internet access benefits the hospital and its patients by facilitating the maintenance of up-to-date, accurate medical records and the availability of cutting edge medical information (66 FR 921). To address this, using the Secretary's authority under section 1877(b)(4) of the Act, we finalized a second exception for noncash items or services provided to a physician. The exception at § 411.357(m) for medical staff incidental benefits permits a hospital to provide noncash items or services to members of its medical staff when the item or service is used on the hospital's campus and certain conditions are met, including that the compensation is reasonably related to the provision of (or designed to facilitate) the delivery of medical services at the hospital and the item or service is provided only during periods when the physician is making rounds or engaged in other services or activities that benefit the hospital or its patients (66 FR 921). In addition, the compensation may not be offered in a manner that takes into account the volume or value of referrals or other business generated between the parties. Under the exception, permissible noncash compensation is limited on a per-instance basis, and the current limit is $36 per instance. Like the exception at § 411.357(k) for nonmonetary compensation, the exception at § 411.357(m) for medical staff incidental benefits does not impose any documentation or signature requirements.

Through our administration of the SRDP, we have been made aware of numerous nonabusive arrangements under which a limited amount of remuneration was paid by an entity to a physician in exchange for the physician's provision of items and services to the entity. In some instances, the arrangements were ongoing service arrangements under which services were provided sporadically or for a low rate of compensation; in others, services were provided during a short period of time and the arrangement did not continue past the service period. For example, one submission to the SRDP disclosed an arrangement with a physician for short-term medical director services while the hospital was finalizing the engagement of its new medical director following the unexpected resignation of its previous medical director. Despite the hospital's need for the services and compensation that was fair market value and not determined in any manner that took into account the volume or value of the referrals or other business generated by the physician, the arrangement could not satisfy all the requirements of any applicable exception because the compensation was not set in advance of the provision of the services and was not reduced to writing and signed by the parties. Under arrangements such as this, insofar as the hospital paid the physician in cash, the exception at § 411.357(k) for nonmonetary compensation would not apply to the arrangement. Similarly, the exception at § 411.357(l) for fair market value compensation would not protect the arrangement if it was not documented in contemporaneous signed writings and the amount of or formula for calculating the compensation was not set in advance of the provision of the items or services, even if the compensation did not exceed fair market value for actual items or services provided and was not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician.

In the proposed rule, we stated that, based on our review of numerous arrangements in the SRDP, we believe that the provision of limited remuneration to a physician would not pose a risk of program or patient abuse, even in the absence of documentation regarding the arrangement and where the amount of or a formula for calculating the remuneration is not set in advance of the provision of items or services, if: (1) The arrangement is for items or services actually provided by the physician; (2) the amount of the remuneration to the physician is limited; (3) the arrangement is commercially reasonable (4) the remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; and (5) the remuneration does not exceed the fair market value for the items or services. We stated that, under these circumstances, remuneration that is held within reasonable limits is unlikely to cause overutilization or similar harms to the Medicare program. Therefore, relying on the Secretary's authority under section 1877(b)(4) of the Act, we proposed an exception for limited remuneration from an entity to a physician for items or services actually provided by the physician (84 FR 55828 through 55829).

We proposed that the exception for limited remuneration to a physician would apply only when the remuneration does not exceed an aggregate of $3,500 per calendar year, which would be adjusted for inflation in the same manner as the annual limit on nonmonetary compensation and the per-instance limit on medical staff incidental benefits; that is, adjusted to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. We stated our belief that an annual aggregate remuneration limit of $3,500 would be sufficient to cover the typical range of commercially reasonable arrangements for the provision of items and services that a physician might provide to an entity on an infrequent or short-term basis. We also proposed that the exception would not be applicable to payments from an entity to a physician's immediate family member or to payments for items or services provided by the physician's immediate family member. We sought public comment on whether the $3,500 annual aggregate remuneration limit is appropriate, too high, or too low to accommodate nonabusive compensation arrangements for the provision of items or services by a physician. We also sought comments regarding whether it is necessary to limit the applicability of the exception to services that are personally performed by the physician and items provided by the physician in order to further safeguard against program or patient abuse. In keeping with our proposal to decouple exceptions issued under our authority at section 1877(b)(4) of the Act from the anti-kickback statute, we did not propose to include a requirement under § 411.357(z) that the arrangement must not violate the anti-kickback statute or other Federal or State law or regulation governing billing or claims submission. However, we solicited comment regarding whether such a safeguard is necessary here in light of the absence of requirements for set in advance compensation and written documentation of the arrangement. We also proposed that the remuneration may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician or exceed fair market value for the items or services provided by the physician, and the compensation arrangement must be commercially reasonable. Finally, we proposed limits on the percentage-based and per-unit compensation formulas for the lease of office space, the lease of equipment, and the use of premises, equipment, personnel, items, supplies, or services (84 FR 55829).

After reviewing the comments, we are finalizing the exception for limited remuneration to a physician at § 411.357(z) with several modifications.

First, we are setting the annual aggregate remuneration limit to the physician at $5,000 instead of at $3,500, adjusted annually for inflation and indexed to the CPI–U. Second, the exception permits the physician to provide items or services through employees whom the physician has hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice). Third, we are requiring that the arrangement is commercially reasonable even if no referrals were made between the parties. Fourth, to address our concerns regarding the preservation of patient choice, we are requiring compliance with the special rule at § 411.354(d)(4) if remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier. Lastly, we are modifying the per-click and percentage-based compensation provisions at § 411.357(z)(1)(v), to clarify that these provisions only apply to timeshare arrangements for the use of premises or equipment.

Given the relatively low annual aggregate remuneration limit of the exception and the other safeguards of the exception, we believe that the exception for limited remuneration to a physician, as finalized, does not pose a risk of program or patient abuse. However, when the remuneration a physician receives from an entity for items or services exceeds the annual aggregate remuneration limit of $5,000, as adjusted annually for inflation, the additional safeguards of other applicable exceptions are necessary to protect against program or patient abuse. For example, for long-term arrangements for items or services provided on a more routine or frequent basis, where the aggregate annual compensation exceeds the annual aggregate remuneration limit of the exception at new § 411.357(z), the requirement that compensation is set in advance before the provision of the items or services is necessary to ensure that various payments made over the term of the arrangement are not determined retrospectively to reward past referrals or encourage increased referrals from the physician. We note that the annual aggregate remuneration limit for the exception at § 411.357(z) is higher than the annual limit for the exception for nonmonetary compensation at § 411.357(k) because the exception for limited remuneration to a physician would protect a fair market value exchange of remuneration for items or services actually provided by a physician, while the exception for nonmonetary compensation does not require a physician to provide actual items or services in exchange for the nonmonetary compensation.

The final exception at § 411.357(z) for limited remuneration to a physician applies to the provision of both items and services by a physician. In the proposed rule, we retracted our prior statements that office space is neither an ''item'' nor a ''service.'' Thus, the exception for limited remuneration to a physician is available to protect compensation arrangements involving the lease of office space or equipment from a physician. For the reasons articulated in section II.D.10. of this final rule and the CY 2017 PFS proposed rule (81 FR 46448 through 46453) and final rule (81 FR 80524 through 80534), the exception at § 411.357(z) incorporates prohibitions on percentage-based and per-unit of service compensation to the extent the remuneration is for the use or lease of office space or equipment, similar to the provisions at existing § 411.357(p)(1)(ii) for indirect compensation arrangements and § 411.357(y)(6)(ii) for timeshare arrangements.

We explained in the proposed rule and reaffirm here our policy that, in determining whether payments to a physician under the exception for limited remuneration to a physician exceed the annual aggregate remuneration limit in § 411.357(z), we will not count compensation to a physician for items or services provided outside of the arrangement, if the items or services provided are protected under an exception in § 411.355 or the arrangement for the other items or services fully complies with the requirements of another exception in § 411.357. To illustrate, assume an entity has an established call coverage arrangement with a physician that fully satisfies the requirements of § 411.357(d)(1) or § 411.357(l). Assume further that the entity later engages the physician to provide supervision services on a sporadic basis during the same year but fails to document the arrangement in a writing signed by the parties. In determining whether the supervision arrangement satisfies the requirements of the exception for limited remuneration to a physician, we will not count the compensation provided under the call coverage arrangement towards the annual aggregate remuneration limit in § 411.357(z). However, if an entity has multiple undocumented, unsigned arrangements under which it provides compensation to a physician for items or services provided by the physician, we consider the parties to have a single compensation arrangement for various items and services, and the aggregate of all the compensation provided under the arrangement may not exceed the annual aggregate remuneration limit of § 411.357(z) during the calendar year in order for the exception to protect the remuneration to the physician. To illustrate, assume the entity in the previous example also engages the physician to provide occasional EKG interpretations during the course of the year, and that the aggregate annual compensation for the supervision services and the EKG interpretation services *taken together* exceeded the annual aggregate remuneration limit.[19] Assuming neither arrangement satisfies the requirements of any other applicable exception, the exception for limited remuneration to a physician will not protect either arrangement (which, as noted, we treat as a single arrangement for multiple services) after the annual aggregate remuneration limit is exceeded during the calendar year.

As we explained in the proposed rule, the exception for limited remuneration to a physician may be used in conjunction with other exceptions to protect an arrangement during the course of a calendar year in certain circumstances (84 FR 55830). To illustrate, assume that an entity engages a physician to provide call coverage services, and that the arrangement is not documented or the rate of compensation has not been set in advance at the time the services are first provided. Further, assume that, after the services are provided and payment is made, the parties agree to continue the arrangement on a going forward basis and agree to a rate of compensation. Assume also that the parties have no other arrangements between them. Depending on the facts and circumstances, the parties may rely on the exception at § 411.357(z) to protect payments to the physician up to the $5,000 annual aggregate remuneration limit, provided that all the requirements of the exception are satisfied. For the ongoing compensation arrangement, the parties could rely on another applicable exception, such as § 411.357(d)(1), to protect the arrangement once the compensation is set in advance and the other requirements of that exception are satisfied. (We remind readers that, under § 411.354(e)(4), the parties would

[19] As noted, compensation paid under the call coverage arrangement would not be included when determining whether the annual aggregate remuneration limit was exceeded, because the call coverage arrangement in this example fully complies with an applicable exception.

have up to 90 consecutive calendar days to document and sign the arrangement.)

In the proposed rule, we noted that § 411.357(d)(1)(ii) requires that the personal service arrangement covers all the services provided by the physician (or an immediate family member of the physician) to the entity (or incorporate other arrangements by reference or cross-reference a master list of contracts) and § 411.357(l)(2) requires that parties enter into only one arrangement for the same services in a year. As we stated in the proposed rule, for purposes of § 411.357(d)(1)(ii), we will not require an arrangement for items or services that satisfies all the requirements of the final exception for limited remuneration to a physician to be covered by a personal service arrangement protected under § 411.357(d)(1) or listed in a master list of contracts (84 FR 55830). Likewise, with respect to the restriction in the exception for fair market value compensation at § 411.357(l)(2), we will not consider an arrangement for items or services that is protected under the exception at § 411.357(z) to violate the prohibition on entering into an arrangement for the same items and services during a calendar year.

The vast majority of commenters supported our proposal, stating that the exception would increase flexibility under our regulations and reduce the burden of compliance without posing a risk of program or patient abuse. After reviewing the comments, we are finalizing the proposed exception for limited remuneration to a physician at § 411.357(z) with certain modifications, as noted above. We are also making certain modifications to the exception for personal service arrangements at § 411.357(d)(1) and the exception for fair market value compensation at § 411.357(l) to ensure that § 411.357(z) may be used in conjunction with these exceptions.

We received the following comments and our response follows.

Comment: We received numerous comments regarding who may provide items and services and to whom the payments for items and services under the new exception at § 411.357(z) may be made. Many commenters requested that we not limit the exception at § 411.357(z) to items or services that are personally provided by physicians. One commenter suggested that the exception should be available for payments to a physician for items or services provided by someone at the direction of and under the control of the physician through a contract or employment arrangement. In contrast, one commenter expressed concern that the exception, as proposed, is subject to abuse and urged CMS to limit the applicability of the exception to items or services that are personally provided by the physician. One commenter suggested that the exception should apply to payments to a group practice for the services of a midlevel practitioner employed by the group or to a physician's immediate family members for items or services provided by the immediate family members.

Response: In the 1998 proposed rule, we interpreted the exception for personal service arrangements at § 411.357(d)(1) to permit physicians to provide services through employees (63 FR 1701). In Phase II, we added that a physician may provide services under § 411.357(d)(1)(ii) through a wholly owned entity or a *locum tenens* physician, but we declined to permit physicians to provide services under the exception through independent contractors (69 FR 16090 through 16093). We explained that, if physicians were permitted to provide services through independent contractors, a physician could enter into a broad range of service arrangements and take a fee as a middleperson without performing any actual service. In contrast, when a physician provides services through an employee or a wholly owned entity, the relationship evidences a *bona fide* business operated by the physician to provide the services. We find this reasoning to be convincing and applicable to the exception for limited remuneration to a physician, and therefore we are clarifying at § 411.357(z)(2) that a physician may provide items or services through an employee, a wholly owned entity, or a *locum tenens* physician, but not through an independent contractor. With respect to items, office space, or equipment provided by a physician through a physician's employee, wholly-owned entity, or *locum tenens* physician, we stress that the items, office space, or equipment provided must be the items, office space, or equipment *of* the physician.

For purposes of determining whether payments comply with the annual aggregate remuneration limit, any payments for items, office space, equipment, or services provided through a physician's employee, wholly owned entity, *or locum* tenens physician would be counted towards the annual aggregate remuneration limit applicable to the physician. In other words, there are not separate limits for a physician and his or her employees. For example, if an entity pays a physician $1,000 for personally performed services, $400 for services provided through the physician's employee, and $150 for items provided through the physician's employee, assuming no other previous payments for the calendar year, the sum of $1,550 is counted towards the annual aggregate remuneration limit applicable to the physician. (See below for a discussion of payments to a group practice or physician organization, and the application of the physician ''stand in the shoes'' rules at § 411.354(c) under the exception for limited remuneration to a physician.) Given our clarification that payments to a physician for items or services provided through a physician's employee, wholly owned entity, *or locum* tenens physician count towards the physician's annual aggregate remuneration limit and the other requirements of the exception, including the low annual compensation limit and requirements pertaining to fair market value, the volume or value of referrals and other business generated, and commercial reasonableness, we do not believe that our final policy poses a risk of program or patient abuse.

We are not convinced that the exception at § 411.357(z) should be applicable to payments to a physician's immediate family member for items or services provided by the family member. As explained above, the limited remuneration to a physician exception is designed in part to allow entities to compensate physicians for short-term or infrequent arrangements, many of which commence under exigent circumstances, with little time to reduce the arrangement to writing or set the compensation in advance. We do not believe that such situations typically arise with respect to physicians' immediate family members. In addition, if each immediate family member had a separate annual aggregate remuneration limit under the exception, the sum total of remuneration to a physician and his or her immediate family members could be substantial, depending on the number of immediate family members. We believe that such a policy may pose a risk of program or patient abuse. We note that an entity is permitted under the exception to compensate a physician for services provided through the physician's immediate family member if the family member is an employee of the physician acting at the direction of the physician, provided that all the requirements of the exception are met. However, as noted above, any payments to the physician for such services would be counted towards the physician's annual aggregate remuneration limit.

Comment: A significant number of commenters supported the proposed exception, but requested that the limit be higher than $3,500 per calendar year,

as adjusted for inflation. Many commenters asserted that the proposed limit of $3,500 could be easily exceeded in a day or a weekend, for example, if a hospital has a sudden and immediate need to secure emergency on-call coverage in an area with high labor costs or a shortage of physicians. Other commenters suggested that a higher annual aggregate remuneration limit would better reflect what they consider the typical range of commercially reasonable arrangements that physicians might enter into with entities on a short-term or infrequent basis. Most commenters requested an annual aggregate remuneration limit of either $5,000, $7,000, or $10,000. A few commenters requested limits over $10,000, such as $35,000 per calendar year or 10 percent of the physician's total cash compensation from an entity (or its affiliates) over the most recent fiscal year. One commenter stated that, as an alternative to raising the annual aggregate remuneration limit, CMS could cap the amount of remuneration per episode of service during a defined period of time, such as 2 or 3 months. In contrast, one commenter urged us to not raise the annual aggregate remuneration limit above $3,500.

Response: In establishing the appropriate annual aggregate remuneration limit in the final exception for limited remuneration to a physician at § 411.357(z), we relied on our experience administering the SRDP and working with law enforcement, as well as comments we received on our proposed rule. In light of the comments we received, we are convinced that the proposed limit of $3,500 per calendar year, as adjusted for inflation, is not high enough to accommodate the broad range of nonabusive infrequent or temporary arrangements that an entity and a physician might enter into over the course of a year. Given the other requirements of the finalized exception, an annual aggregate remuneration limit of $5,000 for items or services actually provided by a physician to an entity does not pose a risk of program or patient abuse. We believe that an annual amount of remuneration greater than $5,000 per calendar year, as adjusted for inflation, may be high enough in certain instances to improperly incent physicians and affect medical decision-making. Without transparency safeguards that require an arrangement to be set forth in writing and signed by the parties and the safeguard of requiring that compensation is set in advance of the provision of items or services under the arrangement, we do not believe that an annual aggregate remuneration limit greater than $5,000 is appropriate. We believe that the per-episode methodology suggested by the commenter would increase burden, be difficult to administer and enforce, and could easily result in failure to comply with the requirements of the exception if parties do not meticulously track payments to the physician. For these reasons, we are finalizing a limit of $5,000 per calendar year, as adjusted for inflation.

Comment: One commenter requested clarification whether the annual aggregate remuneration limit on remuneration applies to an individual physician or a physician practice comprised of more than one physician. Another commenter suggested that the annual aggregate remuneration limit, when applied to physicians in physician organizations, should apply to physicians individually, as opposed to the entire physician organization.

Response: Because the physician self-referral law is implicated when a financial relationship exists between physicians and entities that furnish designated health services, the exception for limited remuneration to a physician at § 411.357(z) is structured to apply to remuneration from an entity to a physician. We did not propose, nor are we finalizing, an exception that permits a specific amount of remuneration from an entity to a physician organization under the conditions outlined in the new exception at § 411.357(z).

Under our regulations at § 411.354(c), remuneration from an entity to a physician organization would be deemed to be a direct compensation arrangement between the entity and each physician who stands in the shoes of the physician organization. A ''deemed'' direct compensation arrangement must satisfy the requirements of an applicable exception if the physician makes referrals to the entity and the entity bills the Medicare program for designated health services furnished as a result of the physician's referrals. The exception for limited remuneration to a physician is available to protect a direct compensation arrangement between an entity providing remuneration to an individual physician, as well as a ''deemed'' direct compensation arrangement between an entity and a physician who stands in the shoes of the physician organization to which the entity provides the remuneration. If an entity that makes payment to a physician organization relies on new § 411.357(z), under § 411.354(c)(1), the payment will create a ''deemed'' direct compensation arrangement with each physician who stands in the shoes of the organization. That is, each physician who stands in the shoes of the physician organization will be deemed to have the same compensation arrangement with the entity making the payment to the physician organization. Compensation received by the physician organization under such circumstances is counted towards the annual aggregate remuneration limit of *each* physician who stands in the shoes of the physician organization. For example, if an entity pays a physician organization $1,000 under § 411.357(z) for lease of the physician organization's equipment, and the physician organization consists of two owners (Drs. A and B) who stand in the shoes of the organization, then $1,000 is counted towards the annual aggregate remuneration limit of both Drs. A and B. The $1,000 payment would not count toward the annual aggregate remuneration limit of other physicians in the physician organization who are not required to stand in the shoes of the physician organization and are not treated as permissibly standing in the shoes of the physician organization.

Remuneration from an entity to a physician under a direct compensation arrangement between the entity and the individual physician (as opposed to a ''deemed direct'' compensation arrangement under the stand in the shoes rules) is counted only towards the individual physician's annual aggregate remuneration limit under § 411.357(z). Returning to the example earlier in this response, if, in a direct compensation arrangement under § 411.354(c)(1)(i), the entity paid Dr. A $500 for her services relying on § 411.357(z), assuming no other payments during the calendar year relying on § 411.357(z), the amount counted towards Dr. A's annual aggregate remuneration limit for payments received from the entity under § 411.357(z) would be $1,500; that is, $500 for the services provided under the direct compensation arrangement and $1,000 for the equipment rental arising from the ''deemed'' direct compensation arrangement with the physician organization. Importantly, the $500 paid under the direct compensation arrangement between the entity and Dr. A would not be counted towards the annual aggregate remuneration limit of Dr. B or any other physician in the physician organization.

Under certain circumstances, a payment from an entity to a physician organization may be considered to be a payment directly to the physician who provided the items or services to the entity, with the physician organization only passing the remuneration through

from the entity to the physician. What constitutes a direct compensation arrangement with an individual physician under § 411.354(c)(1)(i), as opposed to an arrangement with a physician organization that creates a ''deemed direct'' compensation arrangement with a physician standing in the shoes of the organization under § 411.354(c)(ii) or (iii), depends on the facts and circumstances of each arrangement. Important factors include, but are not limited to, whether the physician (or the physician's employee, wholly owned entity, or *locum tenens* physician) provides the services under the arrangement, as opposed to the services being provided by another physician in the physician organization (or the physician organization's employee, wholly owned entity, or *locum tenens* physician); whether any items, office space, or equipment provided by the physician under the arrangement are owned or leased by the individual physician (as opposed to being owned or leased by the physician organization); and whether payment is made directly to the individual physician or, if payment is made to the physician organization, whether the physician organization acts as a pure go-between or middleman, transferring all of the compensation received from the entity under the arrangement to the physician who provided the items or services. (See section II.D.9. of this final rule for a discussion of our policy on pure ''pass-through'' payments.) Payments made to and retained by a physician organization for services provided through an employee of the physician organization are permitted under § 411.357(z), but the payment amount would be counted toward the annual aggregate remuneration limit of each physician who stands in the shoes of the organization.

Comment: A number of commenters requested clarification whether, if compensation exceeds the proposed annual aggregate remuneration limit in a given calendar year (as adjusted for inflation), the entity can rely on the exception up to the point immediately prior to when the remuneration exceeded the limit. The commenters also requested clarification on how the exception would apply when remuneration straddles a calendar year. Specifically, the commenter asked if the remuneration limit resets at the beginning of each calendar year, or whether CMS would apply the exception for a different period, such as a 12-month period beginning with the commencement of the compensation arrangement.

Response: An entity may rely on the exception at § 411.357(z) up to the point in a calendar year immediately prior to when the annual aggregate remuneration limit is exceeded. After that point, if the arrangement does not fit into another applicable exception, the physician is not permitted to make referrals to the entity for designated health services, and the entity may not bill Medicare for such improperly referred services. For example, if the aggregate payments from an entity to a physician exceed the annual aggregate remuneration limit on April 1 of a given year, the exception is available to protect referrals from January 1 to March 31, but not for referrals from April 1 to December 31. We stress, however, that structuring arrangements to satisfy the requirements of an applicable exception that does not impose a cap on the amount of remuneration paid to the physician under the arrangement (other than the requirement that compensation is fair market value for the items and services provided by the physician) is a best practice and the best way to avoid exceeding the annual aggregate remuneration limit imposed at § 411.357(z)(1).

The annual aggregate remuneration limit on remuneration under § 411.357(z) resets each calendar year. As explained in section II.D.2.e. of this rule, the provision of remuneration in the form of items or services commences a compensation arrangement at the time the items or services are provided, and the compensation arrangement must satisfy the requirements of an applicable exception *at that time* if the physician makes referrals for designated health services and the entity wishes to bill Medicare for such services. Thus, for arrangements that straddle a calendar year, remuneration should be allocated to the annual aggregate remuneration limit of a calendar year based on the date that the items or services are provided. To illustrate, assume that an entity engages a physician to present at an educational program series held periodically throughout an academic year spanning September 2020 through May 2021. Assume also that, on December 15, 2020, the entity pays the physician $2,000 for services provided during the fall semester and, on May 15, 2021, the entity pays the physician $4,000 for services provided during the spring semester. The $2,000 paid under the arrangement for the fall semester is counted toward the annual aggregate remuneration limit for 2020 and the $4,000 paid for the spring semester is counted toward the annual aggregate remuneration limit for 2021.

It is possible that the services for which the physician is paid will more directly straddle the change from one calendar year to the next. For example, assume a physician is engaged to provide a single weekend of emergency call coverage and is paid $2,000 for coverage provided on December 31, 2021 and January 1, 2022, and the physician is paid for the services on January 31, 2022. Assuming no unusual circumstances that would require the payment to be weighted for one day over another, $1,000 would be counted towards the physician's 2021 annual aggregate remuneration limit and $1,000 would be counted towards the physician's 2022 annual aggregate remuneration limit.

Comment: One commenter requested that CMS clarify whether the exception for limited remuneration to a physician can apply to multiple types of services or arrangements.

Response: During any given calendar year, the exception at § 411.357(z) may be applied to the provision of different types of items or services, including office space and equipment. The annual aggregate remuneration limit on remuneration from an entity to a physician is determined by adding compensation for all of the various items and services provided by the physician. For example, if, in a calendar year, a physician is paid $500 for one service, $350 for a separate service, $150 for certain items, and $400 for a short-term lease of equipment, the amount allocated to the annual aggregate remuneration limit under § 411.357(z) for that year is $1,400. As explained above, if the parties had additional arrangements in the same calendar year that fully satisfied all the requirements of an applicable exception other than § 411.357(z), the remuneration under those arrangements would not be counted towards the physician's annual limit under § 411.357(z).

Comment: One commenter expressed concern that the exception for limited remuneration to a physician may allow for business arrangements that the commenter deemed ''questionable'' and asserted are subject to abuse. This commenter urged CMS to include additional safeguards in the exception, including a requirement that the arrangement does not violate the anti-kickback statute or other Federal or State law or regulation governing billing or claims submission. Other commenters objected to including any additional requirements pertaining to the anti-kickback statute or Federal or State laws or regulations governing

billing or claims submissions. These commenters stressed that parties already have an independent obligation to not violate these other laws and expressed concern that the introduction of the intent-based anti-kickback statute into the strict liability framework of the physician self-referral law would increase the burden of compliance without affording any additional safeguards to protect against program or patient abuse.

Response: As explained in sections II.D.1. and II.D.10. of this final rule, we generally believe that certain regulatory exceptions need not include requirements pertaining to the anti-kickback statute or other Federal or State laws or regulations governing billing or claims submissions in order to ensure that financial relationships to which the exceptions apply do not pose a risk of program or patient abuse. Even so, we believe that a requirement for compliance with the anti-kickback statute is appropriate in certain instances, particularly where both a regulatory and statutory exception could apply to an arrangement and the regulatory exception does not contain all of the requirements or safeguards that are included in the statutory exception. For example, as explained in section II.D.10, the requirement in the regulatory exception for fair market value compensation at § 411.357(l) that the arrangement does not violate the anti-kickback statute acts as a *substitute* safeguard for certain requirements that are included in the statutory exception for the rental of office space but omitted in the regulatory exception, such as the exclusive use requirement at section 1877(e)(1)(A)(ii) of the Act and § 411.357(a)(3) of our regulations. With respect to the final exception for limited remuneration to a physician at § 411.357(z), the regulatory exception omits certain requirements that are found in many statutory exceptions that are potentially applicable to arrangements excepted under § 411.357(z), such as the set in advance, writing, and signature requirements. However, the low annual cap on aggregate remuneration under the exception provides a strong and sufficient substitute safeguard for the omitted requirements. Therefore, we are not requiring under § 411.357(z) that the arrangement not violate the anti-kickback statute or other Federal or State law or regulation governing billing or claims submissions. Nonetheless, we agree with the commenter that certain additional safeguards are necessary to prevent program or patient abuse, especially in light of our final policy to raise the annual aggregate remuneration limit under the exception from $3,500 to $5,000.

As proposed, the exception for limited remuneration to a physician required the compensation arrangement to be commercially reasonable. As explained elsewhere in this final rule, we believe that the requirement that an arrangement is commercially reasonable is uniformly interpreted wherever it appears. Most exceptions that include a commercial reasonableness requirement, including exceptions that apply to arrangements that could also be excepted by § 411.357(z), stipulate that the arrangement must be commercially reasonable ''even if no referrals were made'' between the parties. We are modifying the requirement at § 411.357(z)(1)(iii) to clarify that the arrangement must be commercially reasonable ''even if no referrals were made between the parties.'' We are concerned that, without this modification, some stakeholders may believe that the commercial reasonableness standard in § 411.357(z) is a different and less demanding standard than the commercial reasonableness requirement in other exceptions.

Because we do not have the same transparency into arrangements protected under the finalized exception at § 411.357(z) and, as explained elsewhere in this final rule, because we prioritize the protection of patient choice, we are also requiring at § 411.357(z)(1)(vi) that, if remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement must satisfy all the conditions of § 411.354(d)(4). As revised in this final rule, § 411.354(d)(4) provides that, if a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, then certain conditions must be met, including that the compensation is set in advance for the duration of the arrangement; the requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties; and neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the volume or value of the physician's referrals to the particular provider, practitioner, or supplier. As explained in section II.B.4. of this final rule, the conditions in § 411.354(d)(4) play an important role in preserving patient choice, protecting the physician's professional medical judgment, and avoiding interference in the operations of a managed care organization. Furthermore, prior to our interpretation of the volume or value standard in this final rule, a service arrangement that included a directed referral requirement would have had to comply § 411.354(d)(4) in order to be deemed not to take into account the volume or value of a physician's referrals to the entity. Given our final rules interpreting the volume or value standard and other business generated standard, to ensure that arrangements excepted under § 411.357(z) protect patient choice and the physician's professional medical judgement and avoid interfering in the operation of a managed care organization, we are requiring compliance with § 411.354(d)(4) for arrangements that condition a physician's compensation on referrals to a particular provider, practitioner, or supplier.

We stress that, under § 411.357(z)(1)(vi), the conditions of § 411.354(d)(4), including the set in advance and writing requirement, must be satisfied only if the arrangement to be excepted under § 411.357(z) conditions a physician's compensation on referrals to a particular provider, practitioner, or supplier. To be excepted under § 411.357(z), an arrangement need not satisfy the conditions of § 411.354(d)(4) if compensation under the arrangement to be excepted is not conditioned in this manner, even if the parties have other, separate arrangements that condition a physician's compensation on referrals to a particular provider, practitioner, or supplier. Likewise, if the parties begin an arrangement relying on § 411.357(z) and the arrangement at its outset does not condition compensation on referrals to a particular provider, practitioner, or supplier, then the arrangement need not comply with § 411.354(d)(4) at its outset. However, if the entity later requires the physician to refer to a particular provider, practitioner, or supplier, the parties must set the compensation and document the referral requirement in writing in advance of the applicability of the requirement.

Although we are not including a requirement for compliance with the anti-kickback statute in § 411.357(z), we reiterate here that, to the extent that remuneration implicates the anti-kickback statute, nothing in our proposals or this final rule affects the parties' obligation to comply with the anti-kickback statute, and compliance with the exception for limited remuneration to a physician does not necessarily result in compliance with

the anti-kickback statute. As we stated in Phase I, section 1877 of the Act is limited in its application and does not address every abuse in the health care industry. The fact that particular referrals and claims are not prohibited by section 1877 of the Act does not mean that the arrangement is not abusive (66 FR 879).

Comment: One commenter requested that we limit the applicability of the exception for limited remuneration to a physician to service arrangements and not permit use of the exception for the rental of office space or equipment or for timeshare arrangements. The commenter stated that such arrangements carry a heightened risk and, therefore, should be documented in writing so that they can be audited, monitored, and objectively verified.

Response: Although we appreciate the importance of ensuring that an exception issued by the Secretary under his authority at section 1877(b)(4) of the Act does not undermine the integrity of the Medicare program, we believe that the safeguards incorporated in final § 411.357(z), including the annual aggregate remuneration limit capping the total remuneration permissible under the exception at a relatively low level and the requirement that the remuneration is for items or services actually provided by the physician, are sufficient to protect against program or patient abuse even with respect to arrangements for the rental of office space or equipment and timeshare arrangements. Therefore, the final exception for limited remuneration to a physician at § 411.357(z) is not limited to arrangements for items and services that are not office space or equipment. The prohibitions on percentage-based compensation and per-unit of service (''per-click'') fees for the rental or use, as modified in this final rule, of office space and equipment serve to protect against certain abusive arrangements.

Comment: Some commenters requested that CMS not finalize the proposed prohibition on certain percentage-based and per-unit of service compensation formulas for the use of premises, equipment, personnel, items, supplies, or services under a timeshare arrangement. The commenter assumed that the proposed requirement is apparently intended to address timeshare arrangements and other arrangements similar to traditional lease of office space and equipment, but asserted that the requirement, as drafted, is so broad that its scope is unclear.

Response: The commenter is correct that the requirement prohibiting a compensation formula under a timeshare arrangement that is based on percentage of revenue or per-unit of service fees that are not time-based relates to the use of premises (including office space), and equipment protected under final § 411.357(z). Under timeshare arrangements, where dominion and control are not transferred for the use of premises, equipment, personnel, items, supplies, or services, we believe that prohibitions on percentage-based compensation and per-unit of service fees are required to ensure that excepted timeshare arrangements do not pose a risk of program or patient abuse. (*See* 80 FR 71331 through 71332.) Therefore, we are not convinced that § 411.357(z)(1)(v) should be removed. However, we agree that the requirement, as proposed, could have an unintended impact on arrangements other than timeshare arrangements, and we are revising the requirement to address our specific concern. Under final § 411.357(z)(1)(v), compensation for the use of premises (including office space) or equipment may not be determined using a formula based on: (1) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises (including office space) or equipment; or (2) per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises (including office space) or equipment.

Comment: Several commenters supported our policy that the exception for limited remuneration to a physician be used in conjunction with other exceptions during the course of a calendar year, noting that the exception, if finalized, would provide relief for parties that begin an arrangement for items or services before the arrangement squarely fits in another exception. One commenter requested that we finalize certain modifications to the exceptions for personal service arrangements at § 411.357(d) and fair market value compensation at § 411.357(l) to ensure consistency with our policy regarding the application of § 411.357(z). Specifically, the commenter requested that we revise § 411.357(d)(1)(ii) to explicitly provide that an arrangement that satisfies all the requirements of § 411.357(z) need not be covered by a personal service arrangement protected under § 411.357(d)(1) or be listed on a master list of contracts. Similarly, the commenter requested that we revise § 411.357(l)(2) to explicitly provide that, if an arrangement for items or services fully satisfied the requirements of § 411.357(z), the parties could also rely on § 411.357(l) to except an arrangement for the same items and services during a calendar year.

Response: As explained in the proposed rule and in this final rule, the exception at § 411.357(z) may be used during the course of a calendar year in conjunction with other exceptions to the physician self-referral law. The commenters are correct that the exception for limited remuneration to a physician may be used in succession with another applicable exception to protect an ongoing arrangement. For example, if parties do not initially document an arrangement or set the compensation in advance, the arrangement may be excepted under § 411.357(z) if all its requirements are satisfied, including that the remuneration does not exceed the annual aggregate remuneration limit established at final § 411.357(z)(1). If the parties continue the arrangement, they may rely on another applicable exception to protect the arrangement on a going forward basis, provided that all the requirements of the other applicable exception are met, including any writing, signature, and set in advance requirements. All the requirements of the other applicable exception, including the set in advance requirement, would have to be met beginning on the date that the parties rely on the other exception, except that the parties would have up to 90 consecutive calendar days to document and sign the arrangement under § 411.354(e)(4). Remuneration provided to a physician for items or services provided prior to the date that the arrangement satisfies all the requirements of an applicable exception other than § 411.357(z) would be counted towards the annual aggregate remuneration limit in § 411.357(z)(1).

The provision at § 411.357(d)(1)(ii) requires that the personal service arrangement covers all the services provided by the physician (or an immediate family member) to the entity, and states that this requirement is met if all the separate arrangements between the entity and the physician (or immediate family member) incorporate each other by reference or if they cross list a master list of contracts. We share the commenter's concern that this requirement could undermine the applicability and utility of the exception for personal service arrangements if the parties to an arrangement concurrently rely on the new exception at § 411.357(z) to protect a separate arrangement for the provision of personal services. Therefore, we are modifying § 411.357(d)(1)(ii) to state

that a personal service arrangement excepted under § 411.357(d)(1) does not have to cover personal services that are provided by a physician under an arrangement that satisfies all the requirement of § 411.357(z). Without this modification, there may be confusion as to whether the exception for limited remuneration to a physician may be used for one service arrangement while the parties concurrently use § 411.357(d)(1) for a separate personal service arrangement. Insofar as personal services provided under an arrangement that satisfies all the requirements at § 411.357(z) are excluded from the ''covers all services'' requirement in § 411.357(d)(1)(ii), it is not necessary to incorporate a personal service arrangement excepted under § 411.357(z) by reference or list it on a master list of contracts.

The exception for fair market value compensation provides at § 411.357(l)(2) that the parties may enter into only one arrangement for the same items or services during the course of a year. We share the commenter's concern that this requirement could undermine the utility of the exception for fair market value compensation if parties first rely on the new exception at § 411.357(z) to protect an arrangement for the same items or services during a single year. (We note that a ''year'' for purposes of the exception at § 411.357(l) is not defined as a ''calendar year'' and refers, instead, to any 365-day period.) We are modifying this provision to state that, other than an arrangement that satisfies all the requirements of § 411.357(z), the parties may not enter into more than one arrangement for the same items and services during the course of a year. With this modification, parties may use the exception for limited remuneration to a physician to protect an arrangement for the provision of items and services, and, during the course of a year, also rely on § 411.357(l) to protect an arrangement for the same items and services.

Comment: One commenter asked for clarification as to whether the proposed exception for limited remuneration to a physician could be relied on by an entity to provide continuing medical education (CME) to physicians for free or at a reduced cost. The commenter characterized our proposal as ''increasing the limit from $300 to $3,500 per year.''

Response: We believe that the commenter is confusing the new exception for limited remuneration to a physician at § 411.357(z) with the exception for nonmonetary compensation at § 411.357(k), which has an annual limit of $300, adjusted annually for inflation. There are significant differences between these exceptions. Among other things, the exception for limited remuneration to a physician protects compensation that does not exceed fair market value for items or services *actually* provided by the physician. Unlike the exception for nonmonetary compensation at § 411.357(k), the new exception at § 411.357(z) does not permit entities to provide remuneration to a physician, including valuable in-kind remuneration such as free or reduced cost CME, without a fair market value exchange for items or services actually provided by the physician. The exception for nonmonetary compensation permits an entity to gift (or otherwise provide) a physician a limited amount of noncash remuneration during the course of a calendar year, not to exceed $300, as indexed to inflation and currently $423 per year, in the aggregate. No exchange of items or services from the physician is required. An entity may provide CME to a physician under the exception at § 411.357(k), provided that the value of the CME does not exceed the annual limit on nonmonetary compensation when aggregated with any other nonmonetary compensation provided to the physician during the same calendar year.

2. Cybersecurity Technology and Related Services (§ 411.357(bb))

Relying on our authority under section 1877(b)(4) of the Act, in the proposed rule, we proposed an exception at § 411.357(bb) (the cybersecurity exception) applicable to arrangements involving the donation of cybersecurity technology and related services (84 FR 55830). We believe that establishing such an exception will help improve the cybersecurity posture of the health care industry by removing a perceived barrier to donations of technology and services that address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the delivery of health care. The OIG is establishing a similar safe harbor to the anti-kickback statute elsewhere in this issue of the **Federal Register**. Despite the differences in the respective underlying statutes, we attempted to ensure as much consistency as possible between the exception to the physician self-referral law and the safe harbor to the anti-kickback statute.

In recent years, both CMS and OIG have received numerous comments and suggestions urging the creation of an exception and a safe harbor, respectively, applicable to donations of cybersecurity technology and related services.[20] The digitization of health care delivery and rules designed to increase interoperability and data sharing in the delivery of health care create abundant targets for cyberattacks. For instance, a large health system with over 400 locations was recently the victim of a system-wide cyberattack that took medication, medical record, and other patient care systems offline.[21] The health care industry and the technology used in health care delivery have been described as an interconnected ecosystem where the weakest link in the system can compromise the entire system.[22] Given the prevalence of electronic health record storage, as well as the processing and transit of health records and other critical protected health information (PHI) between and within the components of the health care ecosystem, the risks associated with cyberattacks that originate with ''weak links'' are borne by every component of the system.

Although we did not specifically request comments on cybersecurity, numerous commenters on the CMS RFI requested that we establish an exception to protect the donation of cybersecurity technology and related services. In response to its request for information specifically related to cybersecurity, OIG received overwhelming support for a safe harbor to protect the donation of cybersecurity technology and related services. Many commenters on both requests for information highlighted the increasing prevalence of cyberattacks and other threats. These commenters noted that cyberattacks pose a fundamental risk to the health care ecosystem and that data breaches result in high costs to the health care industry and may endanger patients. Moreover, disclosures of PHI through a data breach can result in identity fraud, among other things.

The Health Care Industry Cybersecurity (HCIC) Task Force, created by the Cybersecurity Information Sharing Act of 2015

[20] *See,* for example, U.S. Department of Health and Human Services, Office of Inspector General, *Semiannual Report to Congress,* Apr. 1, 2018–Sept. 30, 2018, at 84.

[21] ''Cyberattack hits major hospital system, possibly one of the largest in U.S. History,'' NBC News, September 28, 2020, available at *https://www.msn.com/en-us/news/us/cyberattack-hits-major-hospital-system-possibly-one-of-the-largest-in-u-s-history/ar-BB19vtPQ?li=BBnbcA1.*

[22] *See,* for example, Health Care Industry Cybersecurity Task Force, *Report on Improving Cybersecurity in the Health Care Industry,* June 2017 (HCIC Task Force Report), *available at https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf.*

(CISA),[23] was established in March 2016 and is comprised of government and private sector experts. The HCIC Task Force produced its HCIC Task Force Report in June 2017.[24] The HCIC Task Force recommended, among other things, that the Congress ''evaluate an amendment to [the physician self-referral law and the anti-kickback statute] specifically for cybersecurity software that would allow health care organizations the ability to assist physicians in the acquisition of this technology, through either donation or subsidy,'' and noted that the regulatory exception to the physician self-referral law for EHR items and services and the safe harbor to the anti-kickback statute for EHR items and services could serve as a template for a new statutory exception.[25]

Based on responses to OIG's request for information and our proposed rule, we understand that the cost of cybersecurity technology and related services has increased dramatically, to the point where many providers and suppliers are unable to invest in and, therefore, have not invested in, adequate cybersecurity measures. As previously noted, the risks associated with a cyberattack on a single provider or supplier in an interconnected system are ultimately borne by every component in the system. Therefore, an entity wishing to protect itself by preventing, detecting, and responding to cyberattacks has a vested interest in ensuring that the physicians with whom the entity exchanges data are also able to prevent, detect, and respond to cyberattacks, particularly where the connections allow the physicians to establish bidirectional interfaces with the entity, which inherently present higher risk than connections that permit physicians ''read-only'' access to the entity's data systems. We believe that a primary reason that an entity would provide cybersecurity technology and related services to a physician is to protect itself from cyberattacks; however, we recognize that donated cybersecurity technology and services may have value for a physician recipient insomuch as the recipient would be able to use his or her resources for needs other than cybersecurity expenses. Even so, it is our position that allowing entities to donate cybersecurity technology and related services to physicians will lead to strengthening of the entire health care ecosystem. We believe that, with appropriate safeguards, arrangements for the donation of cybersecurity technology and related services will not pose a risk of program or patient abuse, provided that they satisfy all the requirements of the exception at final § 411.357(bb). In addition, we believe that the exception established in this final rule will promote increased security for interconnected and interoperable health care IT systems without protecting potentially abusive arrangements.

In the proposed rule, we proposed that the exception at § 411.357(bb) would be applicable to nonmonetary remuneration in the form of certain types of cybersecurity technology and related services (84 FR 55831). In an effort to foster beneficial cybersecurity donation arrangements without permitting arrangements that pose a risk of program or patient abuse, we proposed the following requirements for cybersecurity donations made under § 411.357(bb): The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity; neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties; neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor; and the arrangement is documented in writing. After reviewing comments on our proposed rule, we are finalizing the exception for cybersecurity donations and related services at § 411.357(bb) with certain modifications related to the types of nonmonetary remuneration permitted under the exception, as well as nonsubstantive modifications to the text of the regulation.

We received the following general comments and our responses follow.

Comment: The majority of commenters generally supported the proposed exception for cybersecurity technology and related services. Commenters noted that cybersecurity is necessary to enable secure and effective exchange of health information and thus is crucial for care coordination and improved health outcomes. One commenter explained that patient safety is the most critical concern when cyberattacks occur, especially when the cyberattacks impact the patient's electronic health records and medical devices. The commenter added that cyberattacks can result in disclosure of sensitive patient information and can alter the treatment a patient is prescribed, among other negative consequences. One commenter highlighted the trend in health care towards greater interconnectivity, even as costs for cybersecurity rise, and concluded that cybersecurity donations make sense from affordability, efficiency, and social responsibility standpoints. Another commenter stated its belief that health care providers are insufficiently prepared to meet cybersecurity challenges that arise in an increasingly digitized health care delivery system. The commenter stated that the proposed cybersecurity exception would help address these challenges and be part of a national strategy to improve the safety, resilience, and security of the health care industry.

Response: We believe that the exception as finalized at § 411.357(bb) will remove real and perceived barriers to beneficial cybersecurity technology donations, addressing an urgent need to improve cybersecurity hygiene in the health care industry and protect patients and the health care ecosystem overall. With respect to care coordination, we note that, depending on the facts and circumstances, an arrangement for the donation of cybersecurity technology and services may qualify as a value-based arrangement (as defined at final § 411.351) to which the new exceptions at § 411.357(aa)(1), (2), and (3) for arrangements that facilitate value-based health care delivery and payments may be applicable.

Comment: A few commenters generally objected to the proposed cybersecurity exception. One commenter expressed concern that the requirements of the proposed exception are inadequate because, according to the commenter, they are difficult to monitor and less stringent than the requirements of the EHR exception. Another commenter asked CMS to reconsider the exception and whether cybersecurity technology and arrangements involving the donation of such technology are understood sufficiently at this time to warrant an exception. Some commenters expressed concern that the exception could be used to support anti-competitive behavior. One of the commenters maintained that, while health IT donations by large health care entities appear to advance interoperability, the actual result is that physician recipients lose their autonomy as independent providers, the lack of competition increases the costs of health care, and smaller providers are

[23] Public Law 114–113, 129 Stat. 2242.

[24] HCIC Task Force Report, *available at https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf.*

[25] *Id.* at 27.

closed by the larger health system when they do not create a profit. Instead of finalizing the proposal, the commenter urged CMS to fund a program that would allow small or rural providers to gain access to cybersecurity technology. Another commenter expressed concern that the proposed cybersecurity exception could inadvertently bolster information blocking, as some providers cite cybersecurity as a reason for not sharing data or providing data access to physicians.

Response: We do not understand the basis for the commeners' assertions that the provision of cybersecurity items and services to protect information by preventing, detecting, and responding to cyberattacks would limit physician autonomy or lead to inappropriate information blocking. Although we are concerned, in general, about anti-competitive behavior, we believe that an exception for arrangements involving the donation of cybersecurity technology and related services is a necessary and critical tool to assist the health care industry in addressing the prevalent and increasing cybersecurity threats facing the industry, which, among other things, can negatively impact the quality of care delivered to beneficiaries.[26] The cybersecurity exception incorporates many of the core requirements of the EHR exception, including the requirements that: (1) The remuneration is necessary and used predominantly for the purposes outlined in the exception; (2) neither the eligibility of the physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties; (3) neither the physician recipient nor the physician's practice makes the receipt of the technology or services or the amount or nature of the technology or services a condition of doing business with the donor entity; and (4) the arrangement is documented in writing. In addition, as explained above, we believe that many donors will make cybersecurity donations as a self-protective measure. Given these safeguards, we do not believe that the cybersecurity exception, as finalized, permits financial relationships that pose a risk of program or patient abuse.

a. Covered Technology and Services

In the proposed rule, we proposed to limit the applicability of the cybersecurity exception to nonmonetary remuneration consisting of technology or services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity (84 FR 55832).[27] We explained that our goal is to ensure that donations are made for the purposes of addressing legitimate cybersecurity needs of donors and recipients; therefore, the core function of the donated technology or service must be to protect information by preventing, detecting, and responding to cyberattacks (84 FR 55832). As proposed, the exception at § 411.357(bb) would apply to the provision of a wide range of technology and services that are predominantly used for the purpose of, and are necessary for, ensuring that donors and recipients have cybersecurity.

We are taking a neutral position with respect to the types of technology to which the final cybersecurity exception is applicable, including the types and versions of software that an entity may provide to a physician recipient when all the requirements of the exception are satisfied. We did not propose to distinguish, and the cybersecurity exception as finalized here does not distinguish, between cloud-based software and software that must be installed locally (84 FR 55832). The types of technology to which the cybersecurity exception is applicable include, but are not limited to, software that provides malware prevention, software security measures to protect endpoints that allow for network access control, business continuity software, data protection and encryption, and email traffic filtering (84 FR 55832). As we stated in the proposed rule, these examples are indicative of the types of technology that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity (84 FR 55832). In addition, as explained in section II.E.2.b. below, the cybersecurity exception as finalized also applies to hardware that is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. We solicited comments on the scope of the technology to which the cybersecurity exception should be applicable, as well as whether we should expressly include (or exclude) other technology or categories of technology in the exception.

We also proposed that the cybersecurity exception would apply to a broad range of services (84 FR 55832). We stated that such services could include—

- Services associated with developing, installing, and updating cybersecurity software;
- Cybersecurity training services, such as training recipients on how to use the cybersecurity technology, how to prevent, detect, and respond to cyber threats, and how to troubleshoot problems with the cybersecurity technology (for example, ''help desk'' services specific to cybersecurity);
- Cybersecurity services for business continuity and data recovery services to ensure the recipient's operations can continue during and after a cybersecurity attack;
- ''Cybersecurity as a service'' models that rely on a third-party service provider to manage, monitor, or operate cybersecurity of a recipient;
- Services associated with performing a cybersecurity risk assessment or analysis, vulnerability analysis, or penetration test; or
- Services associated with sharing information about known cyber threats, and assisting recipients responding to threats or attacks on their systems.

We stated further that these types of services are indicative of the types of services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity, and solicited comments on the scope of the services to which the cybersecurity exception should be applicable, as well as whether we should expressly include (or exclude) other services or categories of services (84 FR 55832). We noted in the proposed rule and reiterate here that, in all cases, the technology and services provided by an entity must be nonmonetary.

With respect to both technology and services, we emphasize that, although donated technology or services may have multiple uses, the cybersecurity exception only applies to technology and services that are necessary and used predominantly to implement, maintain, and reestablish cybersecurity. The exception does not apply to technology or services that are otherwise used predominantly in the normal course of the recipient's business (for example, general help desk services related to use of a practice's IT). We solicited comment on whether this limitation would prohibit the donation of cybersecurity technology and related services that are vital to improving the

[26] *See,* for example, Health Care Industry Cybersecurity Task Force, *Report on Improving Cybersecurity in the Health Care Industry,* June 2017 (HCIC Task Force Report), *available at https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf.* (recommending an exception for cybersecurity donations).

[27] In the proposed rule, the ''necessary and used predominantly'' condition was included in the proposed regulations at § 411.357(bb)(1)(i). As explained at the end of this section, in the final rule, this condition appears in the chapeau of the exception at § 411.357(bb)(1).

cybersecurity posture of the health care industry.

With respect to the requirement that the technology or services are *necessary* to implement, maintain, or reestablish cybersecurity, we considered, and sought comment on, whether to deem certain arrangements to satisfy this requirement (84 FR 55832). We explained in the proposed rule that such a deeming provision, if adopted, would not affect the requirement that the technology or services are *used predominantly* to implement, maintain, or reestablish cybersecurity. We emphasized that parties would have to show on a case-by-case basis that the ''used predominantly'' requirement is met (84 FR 55832). In the proposed rule, we stated that, if we adopted a deeming provision for the purpose of applying the ''necessary'' requirement at proposed § 411.357(bb)(1)(i), we would deem donors and recipients to satisfy the requirement if the parties demonstrated that the donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework or set of standards (84 FR 55832). Examples of such frameworks and sets of standards include those developed or endorsed by the National Institute for Standards and Technology (NIST), another American National Standards Institute-accredited standards body, or an international voluntary standards body such as the International Organization for Standardization. As explained below in response to comments below, we are not adopting this proposed deeming provision.

We are finalizing our proposal to limit the applicability of the cybersecurity exception to technology and services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. However, in the final cybersecurity exception as established here, we state the scope of the exception in the chapeau of the exception at § 411.357(bb)(1) instead of including a requirement in the exception that the technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. (The remaining requirements of the exception are redesignated to account for this organizational change; for example, proposed § 411.357(bb)(1)(ii) is finalized at § 411.357(bb)(1)(i), and so forth). We are also removing the phrase ''certain types of'' before ''cybersecurity technology and services'' from the chapeau to avoid ambiguity regarding the scope of the exception. Most exceptions to the physician self-referral law are structured such that the chapeau delineates the scope of remuneration that may be provided under the exception, provided that the requirements enumerated under the chapeau language are satisfied. The chapeau of an exception contains specific pre-conditions that must be satisfied in order for the exception to be available to except a particular arrangement. The ''necessary and used predominantly'' condition in the cybersecurity exception serves this function. The remuneration that may be provided under the cybersecurity exception is limited to nonmonetary compensation, consisting of technology and services, that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. In addition, the structural reorganization of the final cybersecurity exception creates greater consistency with the EHR exception. As finalized, the chapeau of the cybersecurity exception mirrors the chapeau in the EHR exception at § 411.357(w)(1), which provides that donated items or services must be necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records. Inclusion of the ''necessary and used predominantly'' condition in the chapeau of the cybersecurity exception underscores that ''necessary and used predominantly'' has the same meaning in both the EHR and cybersecurity exceptions. We believe this consistency is especially important insofar as cybersecurity software may be donated under both exceptions.

We received the following comments and our responses follow:

Comment: One commenter urged CMS to permit, with appropriate safeguards, the donation of both nonmonetary remuneration consisting of cybersecurity technology and services and monetary remuneration to be used for the purchase of cybersecurity technologies and services. The commenter asserted that permitting monetary remuneration in appropriate circumstances could help alleviate what the commenter characterized as the cybersecurity exception's unintended adverse effects on competition, such as a situation where a donor wished to supply cybersecurity technology to two competing small providers and one of the small providers had already purchased the technology but the other had not. The commenter asserted that protecting monetary reimbursement to the first provider and an in-kind donation to the second provider would be fairer than permitting a donation to one competitor and not the other.

Response: We decline to permit reimbursement of previously incurred cybersecurity expenses, as well as the provision of cash remuneration to a physician that is intended to be used for the future purchase of cybersecurity technology and services. We believe that this would pose a risk of program or patient abuse, as the former would simply be a subsidy of practice expenses that a physician—rather than the donor entity—determined to incur, and the latter involves the provision of cash, some or all of which could be used to offset other practice expenses without ultimately enhancing the cybersecurity posture of the donor entity or the health care ecosystem as a whole. We also highlight that the example provided by the commenter likely would not satisfy the other conditions of this exception even if the exception permitted an entity to provide monetary remuneration. For instance, if a physician has already obtained cybersecurity technology or services, the provision of remuneration in the form of reimbursement would not be necessary to implement, maintain, or reestablish cybersecurity.

Comment: A number of commenters supported the requirement at proposed § 411.357(bb)(1)(i) that the technology and related services must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity. One of the commenters suggested that this provision would ensure the legitimacy of donations and help differentiate the technology and services that may be donated under the cybersecurity exception from technology and services that have multiple uses beyond cybersecurity. Another commenter urged CMS to require a clear nexus between the cybersecurity donation and the business relationship between the donor and recipient. The commenter explained that the cybersecurity technology should be necessary for the provision of the services involved, such as where a hospital donates cybersecurity technology to a physician to ensure the secure transfer of personal health information and thus improve care coordination for shared patients. The commenter stated that the cybersecurity exception should not protect donations that are used as a way to entice new business. A different commenter suggested that, provided that donated cybersecurity technology and services substantially further the interests of strengthening cybersecurity for the end user, their donation should be permissible. The commenter agreed with CMS that donors should have the

discretion to choose the amount and nature of cybersecurity technology and services they donate to physicians based on a risk assessment of the potential recipient or based on the risks associated with the type of interface between the parties.

Response: As explained above, the cybersecurity exception is limited to technology and services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. However, we are including this limitation in the chapeau of the final cybersecurity exception rather than as a separate requirement of the exception as we proposed. The change in the organization of the exception does not affect or alter the meaning, scope, or application of the requirement that donated technology and services must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity, as that requirement was explained in the proposed rule (84 FR 55831).

The ''necessary and used predominantly'' language at final § 411.357(bb)(1) delineates the scope of the exception and will ensure that donations are made to address legitimate cybersecurity needs of donors and recipients. With respect to technology and services with multiple uses or functions other than cybersecurity, we note the following. In the 2006 EHR final rule, we acknowledged that electronic health records software is often integrated with other software and functionality, but we explained that such software may still be necessary and used predominantly to create, maintain, transmit, or receive electronic health records if the electronic health records functions predominate (71 FR 45151). We added that the ''core functionality'' of the technology must be the creation, maintenance, transmission, or receipt of electronic health records. The same principle applies to technology (as defined at § 411.357(bb)(2)) and services donated under the cybersecurity exception. While donated technology and services may include functions other than cybersecurity, the core functionality of the technology and services must be implementing, maintaining, or reestablishing cybersecurity, and the cybersecurity use must predominate. Such technology and services must also be necessary for implementing, maintaining, or reestablishing cybersecurity. Although we are not adopting the ''clear nexus'' standard suggested by the commenter, we question whether donated technology or services would be necessary for the donor or recipient to implement, maintain, or reestablish cybersecurity if the technology or services are not connected to the underlying services furnished by either party. We note also that we are finalizing a requirement that a donor may not directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for donated technology or services, or when determining the amount or nature of the donated technology or services. This requirement addresses the concern expressed by the commenters regarding parties that improperly use the exception for donations to entice new business. With respect to the last comment, we decline to adopt the commenter's proposal that donations should be permitted under the cybersecurity exception if the donated technology or services ''substantially further the interests of strengthening cybersecurity for the end user.'' We believe that stakeholders are familiar with the ''necessary and used predominantly'' condition from the EHR exception, and, insofar as the EHR exception applies to cybersecurity software and services, we believe that it reduces administrative burden to use a similar standard for both the EHR and cybersecurity exceptions.

Comment: Most commenters recommended that we finalize an exception that covers a broad range of cybersecurity technology and services, and some requested specific language or clarifications. In particular, several commenters asked CMS to consider how the proposed exception would apply to cloud-based and subscription-based products and services. One commenter supported many of the examples from the proposed rule of services that could be covered under the cybersecurity exception, while other commenters requested that CMS provide clarity related to the scope of potentially permissible donations through additional examples of the types and amounts of technology and services allowed. Specifically, commenters asked CMS to clarify whether the exception is applicable to the following services: Assurance, assessment, and certification programs that allow physicians to assess their own cybersecurity and demonstrate that they are trusted participants in health care data exchange; risk assessment and gap analysis services; consulting services to work with a physician to develop and implement specific cybersecurity policies and procedures; subscription fees required by vendor security products that assist physicians in developing policies and procedures in support of a risk assessment; implementation, management, and remediation services; and provision of a full-time cybersecurity officer. Some commenters noted that a cybersecurity-specific help desk may not be realistic and recommended that CMS permit donations of general help desk services, whether through the donor's IT department or the vendor's help desk services.

Although many commenters expressed concern about the utility of the exception if it does not apply to a broad enough scope of technology and services, other commenters recommended limiting the scope of cybersecurity technology and services that may be provided to a physician under the exception. One of these commenters cautioned against permitting donations of ''cybersecurity as a service.'' The commenter asserted that the ''cybersecurity as a service'' model, where a third-party manages, monitors, or operates the cybersecurity of a recipient, goes beyond what is reasonable for donated cybersecurity, but did not provide further detail as to how ''cybersecurity as a service'' would pose a risk of program or patient abuse.

Response: As finalized, the exception protects donations of a broad range of technology and services. Cybersecurity technology and services include both locally installed cybersecurity software and cloud-based cybersecurity software. As explained in section II.E.2.b. below, the exception also applies to hardware that is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. We provided multiple examples of items and services to which the cybersecurity exception would apply in the preamble to the proposed rule (84 FR 55832), which is repeated above in this final rule. We continue to believe that the cybersecurity exception is applicable to the examples provided in the proposed rule. We also stated in the proposed rule and reiterate here that ''cybersecurity as a service'' may be protected, including third-party services managing and monitoring the cybersecurity of a recipient. Other than a general statement of caution, the commenter that addressed ''cybersecurity as a service'' did not provide any specific reasons why such a service presents a risk of program or patient abuse, and we see no reason why this cybersecurity format requires a different analysis than cybersecurity installed locally or should be excluded from the scope of the cybersecurity exception. All of the examples provided in the proposed rule

are illustrative only, and the list of examples in the proposed rule is not exhaustive. We intend the exception to be applicable to technology and services that are currently available, as well as technologies and services that will be developed in the future. Donated technology and services, however, must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity. To the extent that the services described by commenters are necessary and used predominantly to implement, maintain, or reestablish cybersecurity, they may be donated under the cybersecurity exception (if all the remaining requirements of the exception are also satisfied).

We recognize that cybersecurity functionality is often incorporated into software or other information technology whose primary use and functionality is not cybersecurity and, further, that certain services may be useful for implementing, maintaining, or reestablishing cybersecurity while also generally serving purposes other than cybersecurity (for example, general IT services that include a cybersecurity component). However, in order for technology or services to be donated under the cybersecurity exception, the core functionality of the technology or services must be implementing, maintaining, or reestablishing cybersecurity, and the cybersecurity use must predominate. For instance, depending on the facts and circumstances of a particular arrangement, donating a virtual desktop that includes access to programs and services beyond cybersecurity software likely would not be protected because the technology would include functions not necessary and predominantly used to implement, maintain, or reestablish cybersecurity, such as, for example, word processing or claims and billing applications. Similarly, the exception is likely not applicable to general IT help desk services, because the services would not be used predominantly for cybersecurity. However, we are aware of cybersecurity-specific software and services that include customer service and help desk features for cybersecurity assistance. The cybersecurity exception is applicable to such help desk services if all the requirements of the exception are satisfied. The cybersecurity exception could also be applicable to services provided through an entity's primary help desk, if the services are necessary and used predominantly for cybersecurity (for example, to report cybersecurity incidents). The provision of a full-time cybersecurity officer in a physician recipient's practice must be necessary, the cybersecurity officer's services must be used predominantly to implement, maintain, or reestablish cybersecurity, and all other requirements of the exception at final § 411.357(bb) must be satisfied in order to avoid violation of the physician self-referral law.

Comment: Several commenters interpreted our discussion in the proposed rule of the difficulty of collecting cost contribution amounts for patches and updates to mean that donations of patches or updates to previously donated technology would not fall within the scope of the cybersecurity exception. The commenters highlighted that patching and updates are critical to managing cybersecurity risks and prohibiting their donation could neutralize any benefits resulting from the cybersecurity exception. One of these commenters noted that, given the fast-paced nature of developments in cybersecurity, it is likely that new tools will need to be deployed on at least an annual basis. The commenters asked that we ensure that the cybersecurity exception, if finalized, applies to ongoing cybersecurity software updates and other patches. Another commenter requested clarification regarding whether the provision to a physician of a routine or critical update would cause an arrangement to fail to satisfy all the requirements of the cybersecurity exception, noting that patching is sometimes given to physicians for free (because it is built into the contracts with vendors), and some patches may be focused on security while others may be more general. A different commenter asked CMS to provide greater clarity regarding donations of replacement technology in light of the rapid development of new cybersecurity technology.

Response: Constant vigilance is required to maintain the cybersecurity of the health care ecosystem, and we agree with the commenters that patching and updates are critical to managing cybersecurity risks. As we discussed in response to previous comments, we are not excluding any particular type of technology or services—including patches and updates—from the application of the final cybersecurity exception. The ongoing donation of cybersecurity patches and updates will not result in noncompliance with the physician self-referral law, provided that all the requirements of the cybersecurity exception (or another applicable exception) are satisfied at the time of their donation. We note that the written documentation evidencing the arrangement for the donation of cybersecurity technology or services may account for the future provision of patches and updates, relieving the parties from developing additional documentation each time a patch or update is issued. Also, as described below in section II.E.2.d., the exception at final § 411.357(bb) does not require a financial contribution from the recipient. Therefore, routine patches and upgrades provided to recipients at no cost will not cause the arrangement between the parties to fall out of compliance with the physician self-referral law, provided that all the requirements of the exception are satisfied at the time of their issuance.

Regarding donations of cybersecurity technology or services to physicians who already have some technology or services, the final exception at § 411.357(bb) does not prohibit the donation of replacement technology; however, an arrangement for the provision of cybersecurity technology and services must satisfy all the requirements of the exception. We note that donating replacement technology could satisfy the requirement that the technology or services are necessary to implement, maintain, or reestablish cybersecurity if, for example, the technology that is replaced is outdated or poses a cybersecurity risk.

Comment: One commenter recommended that CMS clarify the scope of the intended ''object'' to be protected by the cybersecurity technology and services; for example, cybersecurity to protect electronic health records, medical devices, or other IT that uses, captures, or maintains individually identifiable health information. The commenter noted that the proposed cybersecurity exception was silent as to the ''object'' of the cybersecurity protection, and asserted that an explicit statement setting broad parameters about the purpose of donated cybersecurity technology and services would provide guidance and potentially cover future technology advances. Another commenter encouraged CMS to specifically permit donations of technology and services related to medical device cybersecurity.

Response: We decline to set parameters or requirements for the intended ''object'' (or ''subject'') of the cybersecurity protection because we are concerned that this could unintentionally limit the scope of the technology and services to which the cybersecurity exception is applicable. If all the requirements of the exception are satisfied, the exception is applicable to cybersecurity technology and services that, among other things, protect

electronic health records, medical devices, or other IT that uses, captures, or maintains individually identifiable health information.

Comment: One commenter objected to what it considered to be CMS' ''piecemeal'' approach to health care technology, with different exceptions for different types of technology (for example, EHR and cybersecurity) that the commenter asserted must work together to drive care coordination. The commenter urged CMS to broaden the scope of the cybersecurity and EHR exceptions to ensure flexibility to protect technology that can help facilitate the transition to a value-based health care delivery and payment system. The commenter specifically recommended that we make any final cybersecurity exception applicable to data analytics and reporting functionalities. The commenter provided as an example predictive data analytics tools that allow a hospital to identify and decrease the number of high-risk heart failure patients presenting for admission to the hospital or emergency room.

Response: We are not extending the scope of the cybersecurity exception at final § 411.357(bb) to all data analytics and reporting functionality specifically designed to facilitate the transition to a value-based health care delivery and payment system, as requested by the commenter. As illustrated by the commenter's example, the use and purpose of data analytics and reporting functionality may differ significantly from those of cybersecurity technology and services. The cybersecurity exception at § 411.357(bb) is limited to technology and services that are necessary and used predominantly to implement, maintain, and reestablish cybersecurity, and its requirements of the exception at § 411.357(bb) are not designed to adequately protect against Medicare program or patient abuse where data analytics and reporting functionality are provided at no cost (or reduced cost) to a physician. Other exceptions to the physician self-referral law address the items and services described by the commenter. We believe that the requirements of those exceptions are appropriate to protect the Medicare program and its patients from abuse when such remuneration is provided by an entity to a physician (or vice versa). With respect to the commenter's concern regarding a piecemeal approach to exceptions under the physician self-referral law, we note that parties seeking to except an arrangement for the donation of technology are not required to utilize multiple exceptions if the separate functions of the technology and the donation satisfy the requirements of a single exception.

Comment: One commenter that generally opposed the cybersecurity exception maintained that effective cybersecurity protection could require a whole suite of services, such as active management, monitoring, and developing an effective response system if an issue arises, and it may not be possible for an outside entity to provide such a broad range of services. The commenter asserted that more limited donations of cybersecurity technology or services, on the other hand, may not provide effective cybersecurity protection for the recipients and may expose the donor to liability in case of a cyberattack.

Response: As described in our responses to other comments, the final cybersecurity exception applies to a wide range of technology and services that implement, maintain, or reestablish cybersecurity (as defined at final § 411.351). Although we established the cybersecurity exception to address real or perceived barriers to improving the cybersecurity posture of the health care industry, the exception does not apply to all remuneration that may be relevant to cybersecurity needs. The final cybersecurity exception permits technology and services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. The protection afforded under the exception is not limited to cybersecurity that is ''effective.'' In the strict liability context of the physician self-referral law, we are concerned that requiring ''effective'' cybersecurity at § 411.357(bb)(1) may chill otherwise beneficial cybersecurity donations, as donors and recipients may lack the expertise to understand and determine what constitutes ''effective'' cybersecurity or there may be disagreement as to whether cybersecurity measures are ''effective.'' Although donor liability is outside the scope of this rulemaking, we note that nothing in the cybersecurity exception prohibits donors and recipients from addressing such issues through contracts or other agreements.

Comment: A number of commenters supported the inclusion of a deeming provision that would allow donors or recipients to demonstrate that the compensation arrangement satisfies the requirement that the technology or services are ''necessary'' if the donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework, such as those developed by NIST, or guidelines developed by the Department of Health and Human Services Office for Civil Rights (OCR) in collaboration with ONC. One commenter recommended that, in cases where cybersecurity is built into software that gives physicians access to a hospital's computer system, the technology should be deemed to be necessary and used predominantly for cybersecurity. The commenter explained that such a deeming provision is warranted because, as noted in the proposed rule (84 FR 55831), a hospital that has granted physicians access to its system has a vested interest in ensuring that the physicians with whom it shares information are also protected from cyberattacks, particularly where the connections allow the physicians to establish bidirectional interfaces with the entity. A different commenter recommended that any deeming provision remain voluntary, while another commenter supported a deeming provision when the cost of the donation of technology and services exceeds a specified monetary limit. One commenter supported the inclusion of a deeming provision but only if the parties to the donation arrangement, through an independent third party, demonstrate and certify that the donation ensures compliance with a written cybersecurity program or framework that conforms to NIST standards. In contrast, several commenters objected to the inclusion of any deeming provision, maintaining that it would add unnecessary burden without providing any meaningful protection against program and patient abuse. One of these commenters stated that physicians may struggle to understand what ''reasonable conformance'' looks like or when a cybersecurity framework or standard is considered ''widely recognized.''

Response: We are not including a deeming provision for establishing compliance with the condition that donated technology and services are necessary for cybersecurity in the final rule. We are concerned that any deeming provision that is specific enough to address our program integrity concerns will be of limited or no utility for stakeholders. We also agree with the commenter that parties may struggle to understand what ''reasonable conformance'' looks like or when a framework or standard is considered ''widely recognized.'' Without selection of one or more specific frameworks, any deeming provision could be challenging to understand and difficult to enforce. Regarding the commenter's suggestion that software that grants access to a hospital's system should be deemed to

be necessary *and* used predominantly for cybersecurity, we agree that the type of connection between a donor and a physician (bidirectional read-write connection versus unidirectional read-only access) is an important factor in determining whether particular technology or services are necessary for cybersecurity. However, we do not believe that any software or other information technology should be *deemed* to be necessary for cybersecurity simply because the technology permits a physician to access a hospital's computer system. Moreover, the determination of whether technology or services are *used predominantly* to implement, maintain, or reestablish cybersecurity depends on how the donated technology or services are used *in fact* and, therefore, not appropriate for a deeming provision. Although technology or services donated under the cybersecurity exception may have uses or functions other than cybersecurity (for example, software that allows a physician to access a hospital's computer system), the cybersecurity use must in fact predominate.

b. Definitions of ''Cybersecurity'' and ''Technology''

In the proposed rule, we proposed to define the term ''cybersecurity'' to mean the process of protecting information by preventing, detecting, and responding to cyberattacks and to define the term ''technology'' to mean any software or other type of information technology, other than hardware (84 FR 55831). Because the term ''cybersecurity'' also appears in the EHR exception at § 411.357(w), which expressly applies to the donation of cybersecurity software and services, we proposed to include the definition of ''cybersecurity'' in our regulations at § 411.351. Because the term ''technology,'' as used in the new exception for cybersecurity technology and related services, would be defined solely for purposes of the exception at § 411.357(bb), we proposed to include its definition at § 411.357(bb)(2) (84 FR 55831). We note that the term ''technology'' is included in several instances in our regulations as part of the term ''information technology'' and at § 411.357(w)(6)(iv) to describe one of the ways in which the determination of the eligibility of a physician for a donation of EHR items or services, or the amount or nature of the items or services, would be deemed not to be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. The proposed definition of ''technology'' was not intended to affect the meaning of the term ''information technology'' or the interpretation of § 411.357(w)(6)(iv).

In the proposed rule, we proposed a broad definition of ''cybersecurity'' derived from the NIST Framework for Improving Critical Infrastructure,[28] a framework that does not apply specifically to the health care industry, but applies generally to any United States critical infrastructure (84 FR 55831). We proposed a broad definition of ''cybersecurity'' to avoid unintentionally limiting donations by relying on a narrow definition or a definition that might become obsolete over time, although we solicited comments whether a definition tailored to the health care industry would be more appropriate (84 FR 55831). We proposed a similarly broad definition of ''technology'' that is neutral with respect to the types of cybersecurity technology to which the exception applies (84 FR 55831). We explained in the proposed rule that the definition of ''technology'' is broad enough to include cybersecurity software and other IT, such as an Application Programming Interface (API)—which is neither software nor a service, as those terms are generally used—that is available now, as well as technology that may become available as the industry continues to develop. As proposed, ''technology'' would have excluded hardware. We explained our concern in the proposed rule that donations of valuable multiuse hardware could pose a risk of program or patient abuse (84 FR 55832).

In the proposed rule, we also considered two alternative proposals that would allow for the donation of certain cybersecurity hardware (84 FR 55831 through 55832). Under the first alternative proposal, the cybersecurity exception would cover certain hardware that is necessary for cybersecurity, provided that the hardware is stand-alone (that is, is not integrated within multifunctional equipment) and serves only cybersecurity purposes (for example, a two-factor authentication dongle). We solicited comments on what types of hardware might meet these criteria and whether such hardware should fall within the scope of the exception. Under the second alternative proposal, parties would be permitted to make more robust donations of cybersecurity hardware if the donor had a cybersecurity risk assessment that identifies the recipient as a risk to its cybersecurity, and the recipient had a cybersecurity risk assessment that provided a reasonable basis to determine that the donated cybersecurity hardware is needed to address a risk or threat identified by a risk assessment (84 FR 55834).

We noted in the proposed rule and reiterate here that the exception at § 411.357(bb), both as proposed and finalized, covers only items and services that qualify as cybersecurity technology and services (84 FR 55832). It does not extend to other types of cybersecurity measures outside of technology or services. For example, the exception does not apply to donations of installation, improvement, or repair of infrastructure related to physical safeguards, even if they could improve cybersecurity (for example, upgraded wiring or installing high security doors). Donations of infrastructure upgrades are extremely valuable and have multiple benefits in addition to cybersecurity, and, thus, permitting an entity to provide such services at no cost to the physician recipient would present a risk of program or patient abuse.

As explained in more detail below, in response to comments we are finalizing the definition of ''cybersecurity'' as proposed, and finalizing the definition of ''technology'' without the phrase ''other than hardware.''

We received the following comments and our responses follow.

Comment: Several commenters agreed with the proposed industry-neutral definition of ''cybersecurity,'' derived from the NIST Cybersecurity Framework (NIST CSF), and most commenters generally agreed that the final rule should include a broad definition of ''cybersecurity'' to provide sufficient flexibility for future changes, adaptations, and variations in the dynamic world of cybersecurity. One commenter was generally supportive of the proposed definition of ''cybersecurity'' but believed it should include the process of protecting information through ''identifying'' and ''recovering'' from cyberattacks in order to account for the entire lifecycle of a cyberattack. The commenter presumed that the addition of ''recovering'' would protect ''back-up services'' that support reestablishing cybersecurity and reduce the impact of ransomware extortion. Another commenter supported the definition of ''cybersecurity'' for being fairly broad and including donations of APIs, but requested that we modify the definition to account for what the commenter identified as the three pillars of information security: Confidentiality of information, integrity of information, and availability of information.

[28] Appendix B, Version 1.1 (April 16, 2018) *available at https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf.*

Response: We agree with the commenters that we should adopt a broad, industry-neutral definition of ''cybersecurity.'' Consequently, we are finalizing a definition derived from the NIST CSF. The NIST CSF is industry-neutral and widely accepted across public and private sectors and international organizations, and it applies to any critical infrastructure in the United States, which includes health care. It provides a commonly understood language for donors and recipients seeking to use the cybersecurity exception to improve their cybersecurity posture. We are not adopting a definition of ''cybersecurity'' that would incorporate specific technology solutions for cyberattacks. We are concerned that, as new cybersecurity technologies are developed and implemented, a definition that incorporates specific technology solutions for cyberattacks could become obsolete. We believe that the final definition of ''cybersecurity'' at § 411.351 provides sufficient flexibility while also permitting parties a clear understanding of the technology to which the exception is applicable. Although the cybersecurity exception does not require compliance with the NIST CSF, we encourage potential donors and recipients to ensure a comprehensive, systematic approach to identifying, assessing, and managing cybersecurity risks.

We decline to add the terms ''identifying'' and ''recovering'' to the definition of ''cybersecurity,'' as suggested by the commenter, and we noted that these terms also appear in the NIST CSF. The NIST CSF organizes basic ''cybersecurity activities'' into five functions: Identify, protect, detect, respond, and recover. The exception at final § 411.357(bb) applies to donations of cybersecurity technology and services that are necessary and used predominantly for one or more of these five functions and the related subfunctions and cybersecurity outcomes that are part of the NIST CSF. We are not persuaded to adopt a more specific definition of cybersecurity by incorporating additional terminology from the NIST CSF and are finalizing the definition of ''cybersecurity'' at § 411.351 as proposed. With respect to recovering from cyberattacks in particular, we stress that, although the cybersecurity exception applies to donations of nonmonetary remuneration consisting of technology and services that are necessary and used predominantly for *reestablishing* cybersecurity, ''reestablishing'' cybersecurity does not include payment by an entity of any ransom on behalf of a physician recipient in response to a cyberattack (or to reimburse a physician for a ransom paid by the physician). Moreover, the payment or reimbursement of a ransom would not be nonmonetary remuneration.

We also decline to modify the definition of ''cybersecurity'' to expressly include the three pillars of information security, as requested by the last commenter. We agree that the concepts described by the commenter as the ''three pillars'' of confidentiality, integrity, and availability of information are fundamental aspects of cybersecurity. The NIST CSF similarly recognizes these concepts; an outcome category under the ''protect'' function of cybersecurity includes management of data ''consistent with the organization's risk strategy to protect the confidentiality, integrity, and availability of information.'' Therefore, the final definition of ''cybersecurity'' at § 411.351, which includes ''the process of protecting information,'' accounts for these principles while also providing flexibility and certainty to donors as to the scope of the cybersecurity exception.

Comment: One commenter stated that the proposed definition of ''cybersecurity'' seems oversimplified and not comprehensive. The commenter suggested that the definition of ''cybersecurity'' should be inclusive of any unauthorized use, even without deliberate criminal activity or a specific cyberattack, and recommended broadening the definition accordingly. A different commenter maintained that the proposed definition of ''cybersecurity'' fails to capture all aspects of security controls relevant to patient information, systems processing, or retention of patient information. The commenter recommended that we define ''cybersecurity'' to mean: (1) The prevention of damage to, protection of, and restoration of computers, electronic communications systems, electronic communications services, wire communication, and electronic communication, including information contained therein, to ensure its availability, integrity, authentication, confidentiality, and nonrepudiation; (2) the prevention of damage to, unauthorized use of, exploitation of, and—if needed—the restoration of electronic information and communications systems, and the information they contain, in order to strengthen the confidentiality, integrity and availability of these systems; or (3) the process of protecting information by preventing, detecting, and responding to attacks.

Response: We decline to modify the definition of ''cybersecurity'' as suggested by the first commenter. We disagree with the commenter's characterization of the definition, and do not believe that the final definition of ''cybersecurity'' at § 411.351 has the effect of limiting donations of cybersecurity technology and services to only those that prevent criminal misconduct. The definition of ''cybersecurity'' adopted in this final rule is unrelated to the intent—criminal or otherwise—of an ''unauthorized user.'' We believe that the definition adopted in this final rule is broad enough to address the commenter's concerns about unauthorized users.

We are also not adopting the definition suggested by the second commenter. The principles underlying the commenter's definition, which the commenter stated are derived from NIST and other Federal government sources, are already generally included in the definition of ''cybersecurity.'' Moreover, we are concerned that some of the language suggested by the commenter would greatly expand the scope of the cybersecurity exception and the donation of such technology and services could pose a risk of program or patient abuse. For example, ''restoration of computers, electronic communications systems, electronic communications services, wire communication, and electronic communication,'' could be lead parties to mistakenly believe that the cybersecurity exception applies to donations of technology and services that are not necessary and used predominantly to implement, maintain, or reestablish cybersecurity, such as donations of entire communication systems.

Comment: Most commenters that commented on the proposed definition of ''technology'' generally agreed with using the NIST CSF as a basis for the definition. However, many of these commenters requested that we permit donations of certain cybersecurity hardware under the exception and delete the phrase ''other than hardware'' in the proposed definition of ''technology.'' In support, some commenters asserted that the lines between hardware, software, services, and other technology that is neither hardware, software, nor a service, are increasingly blurred, and noted that such technologies are often packaged together as a bundle. Other commenters suggested that hardware donations are a foundational requirement to operationalize cybersecurity best practices. These commenters asserted that including hardware within the

definition of ''technology'' would allow for more aggressive data security and excluding hardware from the definition is shortsighted and could limit the use of effective cybersecurity measures. A few commenters highlighted that certain cybersecurity software requires specific hardware and requested that we expand the scope of the exception to cover donations of such hardware. For example, a commenter noted that firewalls involve the use of both hardware and software, and suggested that many clinicians would not have the technical knowledge to configure the firewalls. This commenter recommended that we permit the donation of low-cost hardware, potentially up to a dollar threshold that could not be exceeded for the total donation.

Other commenters that supported permitting the donation of hardware under the cybersecurity exception asserted that failing to extend the application of the exception to donations of multifunctional cybersecurity hardware (or software) would limit the utility of the exception because cybersecurity technology often is not standalone in nature. Some of these commenters provided examples of multifunctional hardware they deemed beneficial to cybersecurity hygiene, such as encrypted servers, encrypted drives, network appliances, locks on server closet doors, upgraded wiring, physical security systems, fire retardant or warning technology, and high security doors. Some of these commenters stated that any program integrity concerns with hardware donations are adequately addressed by the requirement that donated technology and services must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity. In contrast, a few commenters generally supported our proposal to exclude hardware from the definition of technology, citing program integrity concerns.

Response: We are modifying the definition of ''technology'' to remove the phrase ''other than hardware.'' Thus, the cybersecurity exception at final § 411.357(bb) is applicable to hardware that is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. We agree with the commenters that our program integrity concerns regarding donations of valuable multifunctional hardware are adequately addressed by making the exception available only to donated technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity, and we do not believe that a monetary cap is necessary. As explained in section II.E.2.a. above, donated technology, including hardware, may include other functionality or uses besides cybersecurity. However, the cybersecurity use must predominate and the core functionality of the hardware must be implementing, maintaining, or reestablishing cybersecurity. The hardware must also be necessary for cybersecurity.

Certain of the examples offered by commenters, including locks on doors, upgraded wiring, physical security systems, fire retardant or warning technology, and high security doors do not qualify as ''technology'' under § 411.357(bb)(2) because they are physical infrastructure improvements, not software or other information technology. Therefore, the cybersecurity exception is not applicable to these items. The cybersecurity exception is applicable to hardware such as encrypted servers, encrypted drives, and network appliances, but *only* if the hardware is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. If, for example, an encrypted server is used predominantly to host the computer infrastructure of a recipient, it would not satisfy the necessary and used predominantly requirement of § 411.357(bb)(1), even if the encrypted server has ancillary cybersecurity uses and functionality.

Comment: A number of commenters suggested that CMS expand the proposed cybersecurity exception to apply to single-function hardware technologies that have limited or no functionality outside of cybersecurity, such as computer privacy screens, two-factor authentication dongles and security tokens, facial recognition cameras for secure access, biometric authentication, secure identification card and device readers, intrusion detection systems, data backup systems, and data recovery systems. One commenter asserted that the sole purpose of most cybersecurity hardware is to maintain the security of patient data.

Response: The final definition of ''technology'' does not preclude hardware and should address the commenters' concerns. We agree that certain hardware is limited to cybersecurity uses. Provided that all the requirements of the exception are satisfied, including the requirement that the donated hardware is necessary and used predominantly to implement, maintain, or reestablish cybersecurity, the exception at § 411.357(bb) will permit the donation of single-use or standalone cybersecurity hardware, including the types described by the commenters.

Comment: We received several comments on our alternative proposal to permit more robust donations of cybersecurity hardware, provided that both the donor and the recipient obtain risk assessments which provide a reasonable basis to determine that the donated cybersecurity hardware is necessary. A number of commenters generally favored the proposal. Some of these commenters asserted that, because the donation is based on the results or recommendations of a risk assessment, there should be no cap or limit on the type or amount of hardware that may be donated and no requirement that a recipient contribute to the cost of donated hardware. Other commenters favored allowing robust donations of cybersecurity hardware, but opposed the requirement in the alternative proposal that both the donor and the recipient first obtain a risk assessment supporting the donation. One commenter stated that the alternative proposal could pose a risk of program abuse, while a different commenter found the alternative proposal to be too limiting, and suggested that hardware donations be permitted if the hardware is necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

Response: We are not adopting a policy that permits the donation of cybersecurity hardware only when the donor has a cybersecurity risk assessment that identifies the recipient as a risk to its cybersecurity, and the recipient has a cybersecurity risk assessment that provides a reasonable basis to determine that the donated cybersecurity hardware is needed to address a risk or threat identified by a risk assessment. We believe that our expansion of the definition of ''technology'' to include hardware, coupled with the requirement that any donated hardware is necessary and used predominantly to implement, maintain, or reestablish cybersecurity, provides sufficient flexibility for cybersecurity hardware donations while protecting against program or patient abuse. Although we are not finalizing this alternative proposal, parties remain free, and are encouraged, to perform risk assessments to determine donor and recipient vulnerability to cyberattacks and to assist in creating their own cybersecurity programs.

Comment: One commenter explained that, typically, entities do not purchase the actual software that provides cybersecurity. Rather, entities purchase the right to use the software, which is accomplished through licensing, and

donate a license to use the software to recipients. In these circumstances, the software itself is not donated. The commenter also recommended that we include installment and repairs among the types of technology and services that may be donated under the exception.

Response: We recognize that, in some instances, entities purchase the right to use cybersecurity software, which is accomplished through licensing, and donate that use or license rather than the software itself. The donation of a license to use cybersecurity software may be permissible under the final exception at § 411.357(bb) in the same way that donating software would be permissible, if all the requirements of the exception are satisfied. We agree with the commenter that installment and repairs should be included among the technology and services to which the cybersecurity exception is applicable, and the final cybersecurity exception is applicable to such services.

c. Requirement for Donors (§ 411.357(bb)(1)(i)) [29]

In the proposed rule, we proposed a requirement that neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties (84 FR 55833). It is our understanding that the purpose of donating cybersecurity technology and related services is to guard against threats that come from interconnected systems, and we expect that a donor would provide the cybersecurity technology and related services only to physicians that connect to its systems, which includes physicians that refer to the donor. However, this requirement would prohibit the donor from directly taking into account the volume or value of a physician's referrals or the other business generated by the physician when determining: (1) Whether to make a donation of cybersecurity technology or services; or (2) how much or the nature of the donated technology or services. We are including this requirement as proposed; however, it is designated in the final regulation at § 411.357(bb)(1)(i).

Nothing in the requirements of the final cybersecurity exception is intended to require a donor to donate cybersecurity technology and related services to every physician that connects to its system. Donors are permitted to select recipients in a variety of ways, provided that neither a physician's eligibility, nor the amount or nature of the cybersecurity technology or related services donated, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For example, a donor could perform a risk assessment of a potential recipient (or require a potential recipient to provide the donor with a risk assessment) before determining whether to make a donation or the scope of a donation. If the donor is a hospital, it might choose to limit donations to physicians on the hospital's medical staff. Or, the donor might select recipients based on the type of actual or proposed interface between them. For example, an entity may elect to provide a higher level of cybersecurity technology and services to a physician with whom it has a higher-risk, bi-directional read-write connection than the entity would provide to a physician with whom it has a read-only connection to a properly implemented, standards-based API that enables only the secure transmission of a copy of the patient's record to the physician.

As discussed in the proposed rule, in contrast to the similar requirement in the EHR exception at § 411.357(w)(6), the cybersecurity exception does not include a list of selection criteria which, if met, would be deemed not to directly take into account the volume or value of referrals or other business generated by the physician (84 FR 55833). We solicited comments on whether we should include deeming provisions in the exception for cybersecurity donations that are similar to the provisions at § 411.357(w)(6), and any other requirements or permitted conduct that we should enumerate in the cybersecurity exception (84 FR 55833). As explained below, we are not adopting deeming provisions for determining compliance with final § 411.357(bb)(1)(i).

We did not propose to restrict the types of entities that may make cybersecurity donations under the cybersecurity exception (84 FR 55833). Although receiving donated cybersecurity technology and related services would relieve a physician of a cost that he or she otherwise would incur, the program integrity risks associated with arrangements for the donation of technology and related services intended to promote cybersecurity are different than those associated with arrangements for the donation of other valuable technology, such as EHR items and services. However, we solicited comments on whether we should narrow the scope of entities that may provide remuneration under the cybersecurity exception as we have done in other exceptions, such as the EHR exception. As explained in section II.E.2.e. below, we are not limiting the types of entities that are permitted to make donations under final § 411.357(bb).

Based on the comments, we are finalizing the requirement that neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties, although it is designated in the final exception at § 411.357(bb)(1)(i). Final § 411.357(bb)(1)(i) is identical to proposed § 411.357(bb)(1)(ii). As noted above and explained more fully below in response to comments, we are not adopting deeming provisions that would allow parties to demonstrate compliance with final § 411.357(bb)(1)(i), and we are not restricting the types of entities that may make donations under the final cybersecurity exception at § 411.357(bb).

We received the following comment and our response follows.

Comment: Commenters generally supported the requirement at final § 411.357(bb)(1)(i) that neither the eligibility of a physician for cybersecurity technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. However, a number of these commenters opposed our proposal to establish a deeming provision, similar to the deeming provision in the EHR exception at § 411.357(w)(6), under which certain selection criteria would be deemed to satisfy the requirement at final § 411.357(bb)(1)(i). One commenter maintained that it would create a risk of program or patient abuse to permit a donor to choose recipients who will receive donations of cybersecurity through a deeming provision. In contrast, other commenters supported the establishment of a deeming provision to provide clarity and guidance with respect to how parties may determine the eligibility of a physician recipient for cybersecurity technology or services, or the nature and

[29] In the proposed rule, the requirement that neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties was designated as § 411.357(bb)(1)(ii). However, this requirement is designated as § 411.357(bb)(1)(i) in this final rule.

amount of such services, without violating the physician self-referral law.

Response: We are finalizing the requirement that neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties, but are not including a list of selection criteria that, if utilized, would be deemed not to directly take into account the volume or value of referrals or other business generated between the parties. As we explained in the proposed rule, deeming provisions for selection criteria that pertain to a prohibition on taking into account the volume or value of referrals or other business generated between parties are sometimes interpreted as prescriptive requirements, especially in the context of a new exception that applies to emerging and rapidly evolving arrangements such as the cybersecurity exception (84 FR 55833). In this context, we are concerned that a deeming provision may cause the parties to an arrangement to forgo legitimate and acceptable selection criteria, thus limiting the scope and utility of the cybersecurity exception. Because we do not want to inhibit appropriate cybersecurity donations that are made using selection criteria that are not expressly deemed to be permissible under the cybersecurity exception, we are not finalizing any deeming provisions pertaining to the requirement at final § 411.357(bb)(1)(i).

d. Requirement for Recipients (§ 411.357(bb)(1)(ii)) [30]

In the proposed rule, we proposed to include in the cybersecurity exception a requirement that neither the physician, nor the physician's practice (including employees or staff members), makes the receipt of cybersecurity technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor (84 FR 55833). This requirement mirrors a requirement in the EHR exception at § 411.357(w)(5). At final § 411.357(bb)(1)(ii), we are finalizing the requirement as proposed.

We did not propose and, thus, are not including in the final cybersecurity exception a requirement that the physician recipient of cybersecurity technology or services must contribute to the cost of the technology or services. As explained earlier in this section II.E.2., with this exception, we seek to remove a barrier to donations that improve cybersecurity throughout the health care industry in response to the critical cybersecurity issues identified in the HCIC Task Force Report, by commenters to the CMS RFI and OIG request for information, and elsewhere. We proposed to include only those requirements under the exception that we believe are necessary to ensure that the arrangements do not pose a risk of program or patient abuse. In the case of cybersecurity technology and related services, we do not believe that requiring a minimum contribution to the cost by the recipient is necessary or, in some cases, practical. We recognize that the level of services for each recipient might vary, and might be higher or lower each year, each month, or even each week, resulting in the inability of certain physician practices, especially solo practitioners or physician practices in rural areas, to make the required contribution, which, in turn, risks the overall cybersecurity of the health care ecosystem of which the practices are a part. Similarly, donors may aggregate the cost of certain services across all recipients, such as cybersecurity patches and updates, on a regular basis, which may result in a contribution requirement becoming a barrier to widespread, low-cost improvements in cybersecurity because of the amount allocated to each recipient. Moreover, if physicians are not required to utilize resources to contribute to the cost of cybersecurity that benefits both the donor and the physician, they will instead have the flexibility to contribute to the overall cybersecurity of the health care ecosystem by using available resources for otherwise unprotected cybersecurity-related hardware that is core to their business, including updates or replacements for outdated legacy hardware that may pose a cybersecurity risk.

Importantly, although the final cybersecurity exception does not require a recipient to contribute to the cost of donated cybersecurity technology or related services, donors are free to structure donation arrangements under § 411.357(bb) to require that recipients contribute to the cost of cybersecurity technology and related services. However, if a donor gave a full suite of cybersecurity technology and related services at no cost to a high-referring practice but required a low-referring practice to contribute 20 percent of the cost, then the donation could violate the requirement at § 411.357(bb)(1)(i).

Based on the comments, we are finalizing the requirement that neither the physician, nor the physician's practice (including employees or staff members), makes the receipt of cybersecurity technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor as proposed.

We received the following comments and our responses follow.

Comment: Several commenters supported the proposed requirement that neither the physician who receives the cybersecurity technology nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor. One of these commenters requested that CMS align its provision on conditioning business on the receipt of cybersecurity technology or services with OIG's safe harbor condition at proposed 42 CFR 1001.952(jj)(3), while another commenter requested that the requirement in the cybersecurity exception mirror the similar requirement in the EHR exception at § 411.357(w)(5).

Response: As proposed and finalized, the prohibition on making the receipt of cybersecurity technology or services a condition of doing business with the donor at final § 411.357(bb)(1)(ii) is substantively identical to the OIG's safe harbor condition at proposed 42 CFR 1001.952(jj)(3) and the similar requirement in the EHR exception at § 411.357(w)(5). Variation in the wording of the regulations reflect differences in the underlying statutes, with respect to the anti-kickback safe harbor, and differences in the application of the EHR and cybersecurity exceptions, with respect to the similar provision in the EHR exception at § 411.357(w)(5).

Comment: Many commenters agreed that we should not require a recipient of cybersecurity technology and services to contribute to the overall cost of the technology and services. Commenters variously asserted that a contribution requirement in the context of cybersecurity may act as a barrier to donations of technology and services because calculations of the cost of technology and services may be imprecise, it may be administratively burdensome to calculate or track contributions, and contributing to the cost of cybersecurity technology and

[30] In the proposed rule, the requirement that neither the physician, nor the physician's practice (including employees or staff members), makes the receipt of cybersecurity technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor was designated at § 411.357(bb)(1)(iii). However, this requirement is designated as § 411.357(bb)(1)(ii) in this final rule.

services may be impossible for some physician recipients. In contrast, several commenters supported a contribution requirement, although one of these commenters suggested that a contribution requirement less than what is required under the EHR exception would be appropriate because, according to the commenter, a 15 percent contribution toward cybersecurity technology and services may be too high for some physicians. A few commenters that supported a contribution requirement suggested that small and rural providers, those in medically underserved areas, and federally qualified health centers should be exempt from any such requirement. A few other commenters suggested that entities should have the choice whether to require a contribution from recipients, with one of these commenters supporting a prohibition on determining the amount of the contribution from the physician recipient in any manner that takes into account the volume or value of the physician's referrals or the other business generated by the physician.

Response: We did not propose and, thus, are not including a contribution requirement in the final cybersecurity exception at § 411.357(bb). For the reasons stated in the proposed rule (84 FR 55833 through 55834), as well as those identified by commenters, we do not believe that it is necessary or advisable to require the physician recipient of cybersecurity technology or services to contribute to the cost of the technology or services. The exception, as finalized, includes sufficient safeguards against program or patient abuse, and it is not necessary to include a contribution requirement that might undermine our goal of facilitating improvement and maintenance of the cybersecurity of the health care ecosystem. As we stated in the proposed rule (84 FR 55834), donors are free to require recipients to contribute to the costs of donated cybersecurity technology and services; however, we caution that the determination of the amount of the required contribution may not take into account the volume or value of the physician recipient's referrals or other business generated between the parties.

e. Written Documentation (§ 411.357(bb)(1)(iii)) [31]

We proposed to require that the arrangement for the provision of cybersecurity technology and related services is documented in writing (84 FR 55834). We stated that, although we would not interpret this requirement to mean that every item of cybersecurity technology and every potential related cybersecurity service must be specified in the documentation evidencing the arrangement, we expect that the written documentation evidencing the arrangement identifies the recipient of the donation and includes the following: a general description of the cybersecurity technology and related services provided to the recipient over the course of the arrangement, the timeframe of donations made under the arrangement, a reasonable estimate of the value of the donation(s), and, if applicable, the recipient's financial responsibility for some (or all) of the cost of the cybersecurity technology and related services that are provided by the donor (84 FR 55834). We did not propose and, thus, we are not including a requirement in the final cybersecurity exception at § 411.357(bb) that the parties sign the documentation that evidences the arrangement or that the parties document their arrangement in a formal signed contract, because we believe that this requirement may lead to inadvertent violation of the physician self-referral law, especially in situations where donors need to act quickly and decisively—prior to obtaining the signature of each physician who is considered a party to the arrangement—to provide needed cybersecurity technology or related services to physician recipients. In the proposed rule (84 FR 55834), we solicited comments on whether we should specify in regulation which terms are required to be in writing. We also sought comment regarding whether we should include a signature requirement in the cybersecurity exception.

Based on the comments, we are finalizing the writing requirement as proposed. It is designated at final § 411.357(bb)(1)(iii). We are not including regulatory text that specifies which terms of the arrangement must be in writing. Rather, we believe that the appropriate standard, as described in the CY 2016 PFS, is that the writing requirement of the exception is satisfied if contemporaneous documents would permit a reasonable person to verify compliance with the exception at the time that a referral is made (80 FR 71315).

We received the following comments and our responses follow.

Comment: Most commenters supported a writing requirement that provides parties with flexibility in compiling the documentation necessary to satisfy the requirement. However, a few commenters supported the inclusion of a requirement to document the arrangement in a formal written agreement, noting that this would provide transparency with respect to the cybersecurity donation process, especially in the case of hardware donations. Another commenter opined that requiring a formal written agreement between the donor and the recipient would be a reasonable safeguard, as long as the requirements for the written agreement are limited in scope. The commenter asked CMS to require documentation only of the technology or services to be donated, commercial terms as necessary to satisfy the requirements of the cybersecurity exception, and warranties by both parties to use the technology in compliance with applicable laws and regulations. The commenter also suggested that, if CMS requires a formal written agreement between the parties, to facilitate compliance, CMS should make available on the CMS website a template agreement with standard terms. In contrast, one commenter requested that CMS not impose ''burdensome'' writing requirements on the parties. The commenter asserted that, although donors have a vested interest in more robust documentation, for example, requiring recipients to acknowledge applicable security rules, CMS should not mandate the documentation of specific information in order for parties to avail themselves of the cybersecurity exception.

Response: We believe that the writing requirement at final § 411.357(bb)(1)(iii) is reasonable in scope, and provides for adequate transparency to protect against program or patient abuse without imposing undue burden. In the proposed rule (84 FR 55834), we stated that written documentation of the arrangement should include a general description of the cybersecurity technology and related services provided to the recipient over the course of the arrangement, the timeframe of donations made under the arrangement, a reasonable estimate of the value of the donation(s), and, if applicable, the recipient's financial responsibility for some (or all) of the cost of the cybersecurity technology and related services that are provided by the donor (84 FR 55834). We are not persuaded to specify which terms of a cybersecurity donation arrangement must be in writing, and we decline to provide a template cybersecurity donation agreement or standard cybersecurity donation terms, as suggested by the commenter. We remind

[31] In the proposed rule, the requirement that the arrangement is documented in writing was designated at § 411.357(bb)(1)(iv). However, this requirement is designated as § 411.357(bb)(1)(iii) in this final rule.

stakeholders that the relevant inquiry for determining compliance with the writing requirement at final § 411.357(bb)(iii) is whether contemporaneous documents pertaining to the arrangement would permit a reasonable person to verify compliance with the cybersecurity exception at the time that a referral is made (80 FR 71315). We believe that providing parties with the flexibility to document their arrangements in any manner that meets this standard is preferable to detailed mandates that could result in noncompliance with the physician self-referral law due to even a slight departure from the documentation requirement. Of course, parties are free to include additional terms in a written agreement related to a cybersecurity donation beyond those required under the exception at § 411.357(bb).

Comment: One commenter requested that CMS address the differences between the documentation and signature requirements in the cybersecurity exception and OIG's cybersecurity safe harbor. The commenter highlighted that the writing requirement in the exception requires that the arrangement is documented in writing but does not require a formal written agreement that is signed by the parties, whereas the corresponding requirement in the OIG's proposed cybersecurity safe harbor requires that the arrangement is set forth in a written agreement that is signed by the parties and describes the technology and services being provided and the amount of the recipient's contribution, if any (84 FR 55765). Another commenter suggested that a signed agreement should be a necessary requirement of the exception, as it would ensure that both the donor and recipient understand what is being donated and the terms of the donation. A different commenter asserted that it is rare that the need for cybersecurity is so pressing that there is not time for parties to prepare and sign an agreement, and supported the inclusion of a signature requirement in the cybersecurity exception.

Response: We are not persuaded to add a requirement that the arrangement is set forth in a single written agreement that is signed by the parties. Although it is a best practice to reduce the key terms of an arrangement to a writing that is signed by the parties, we are concerned that a signature requirement, in particular, could delay an entity's ability to provide necessary and beneficial cybersecurity technology and services to a physician. The physician self-referral law is a strict liability statute, which requires all the requirements of an exception to be satisfied at the time a referral is made. The failure to fully satisfy even a single requirement of an exception triggers the physician self-referral law's referral and billing prohibitions where a financial relationship exists between a physician and an entity that furnishes designated health services. We are concerned that a detailed writing requirement or a signature requirement may result in inadvertent violations. We believe that our current standard for written documentation, which requires contemporaneous documents that would permit a reasonable person to verify compliance with the exception at the time a referral is made, provides sufficient transparency and facilitates compliance (80 FR 71315). For the same reasons, we are not persuaded to include a signature requirement in the cybersecurity exception.

e. Miscellaneous Comments

In addition to the comments discussed above, we received several comments unrelated to our specific proposals and our responses follow.

Comment: One commenter generally supported the proposed cybersecurity exception, but suggested that CMS adopt the same prohibition on cost-shifting that was proposed in the cybersecurity safe harbor. The commenter stated that, although a hospital's own cybersecurity costs could be an administrative expense on its cost report, hospitals should not be permitted to include donations of cybersecurity technology or services to physicians as an administrative expense on the hospital's cost report.

Response: We do not believe that a prohibition on cost-shifting is necessary in the cybersecurity exception. As explained above, we believe that cybersecurity donations are often self-protective in nature, and thus do not pose the same level of risk as donations of EHR items and services. There is no prohibition on cost-shifting in the EHR exception, and we do not believe that such a prohibition is necessary in the cybersecurity exception. We note also that Medicare payment rules and regulations that apply to claims for reimbursement address inappropriate cost-shifting by hospitals through other mechanisms. We believe that, as with the EHR exception, the requirements of the cybersecurity exception, coupled with other Medicare rules and regulations pertaining to cost reports, are sufficient to protect against abusive donations of cybersecurity technology and related services.

Comment: One commenter worried that cybersecurity donations could be used as a gift or financial incentive and maintained that cybersecurity donations should be based on risk assessments of the donor's own software, systems, or networks. In addition, the commenter suggested that cybersecurity donations should be made available to all recipients with similar risk assessments and without regard to business relationships or affiliations. For example, the commenter stated that a donation would be appropriate if the level of connectivity between the donor and recipient created a vulnerability that could be targeted and exploited by malicious actors.

Response: Although donors are permitted under the cybersecurity exception to perform a risk assessment of a potential recipient (or require a potential recipient to provide the donor with a risk assessment) before determining whether to make a donation or the scope of a donation, we decline to require donors to base cybersecurity donations on a risk assessment of either the donor or the recipient. We believe that this requirement would be impractical, and it may lead potential donors to not make otherwise beneficial cybersecurity donations. We also believe it is impracticable that donors would make donations available to all similar recipients with similar risk assessments, independent of the specific cybersecurity needs inherent in connecting to the specific systems with which the donor interacts.

Comment: Several organizations representing individuals and entities in the laboratory industry recommended excluding laboratories from utilizing the cybersecurity exception to provide cybersecurity technology and services to physicians. One commenter opined that the concerns CMS discussed in the 2013 EHR final rule regarding the provision of EHR items and services by laboratory companies similarly apply to cybersecurity donations by these entities. According to another commenter, during the period when laboratories were permitted to donate EHR items and services under the exception at § 411.357(w), physicians implicitly or explicitly conditioned referrals on EHR donations, and EHR vendors encouraged physicians to request costlier EHR software and services from laboratories, putting laboratories in an untenable position. This commenter expressed concern that the same could happen with cybersecurity donations if laboratories are permitted to make donations under the cybersecurity exception, if finalized as proposed. The commenters stated that the proposed requirements of the exception, including both the

requirements at § 411.357(bb)(1)(i) and § 411.357(bb)(1)(ii), would not be sufficient to curb the risk of program or patient abuse.

Response: Although we acknowledge the unique perspective and concerns of the commenters representing the laboratory industry, particularly in light of the laboratory industry's experience with the EHR exception, the final cybersecurity exception does not exclude any type of entity from utilizing the exception. All individuals and entities, including laboratories, play a role in protecting the health care ecosystem from cybersecurity threats. As described in section II.E.2.d., we are finalizing a requirement at § 411.357(bb)(1)(ii) that prohibits a physician (and the physician's practice, including employees and staff members) from making the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor. This requirement is similar to the requirement in the EHR exception at § 411.357(w)(5) and operates in the same manner. We believe that the requirements of the final cybersecurity exception are sufficient to ensure against program or patient abuse. Therefore, we are not categorically excluding laboratory companies from the cybersecurity exception.

Comment: Several commenters requested that CMS permit cybersecurity donations to physicians from organizations that do not furnish designated health services, such as clinical data registries, manufacturers of medical products, and medical technology companies. The commenters stated that medical technology companies play a central role in the delivery of health care, and that such entities should be permitted to make donations that directly relate to the safe and effective use of the registry or the product the entity manufactures. Another commenter requested confirmation that donations made to physicians by organizations that do not furnish designated health services, such as technology firms, do not implicate the physician self-referral law, and that donations made by entities that do furnish designated health services to individuals other than physicians (or immediate family members of physicians) similarly do not implicate the physician self-referral law.

Response: The physician self-referral law's referral and billing prohibitions apply when there is a financial relationship between a physician (or an immediate family member of a physician) and an entity that furnishes designated health services. Financial relationships include direct compensation arrangements between an entity that furnishes designated health services and a physician (or an immediate family member of a physician), as well as indirect compensation arrangements between such parties. Indirect compensation arrangements exist where, among other things, between an entity furnishing designated health services and a physician (or an immediate family member of a physician) there is an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships between them. An organization that does not furnish designated services, such as a technology firm, or an individual who is not a physician may be a ''link'' in such an unbroken chain of financial relationships. If all the conditions of § 411.354(c)(2), as revised in this final rule, exist, there would be an indirect compensation arrangement that implicates the physician self-referral law. If an organization that does not furnish designated health services donates cybersecurity technology or services to a physician (or an immediate family member of a physician), but the donation does not result in an indirect compensation arrangement between that physician (or immediate family member) and an entity that does furnish designated health services, the donation does not implicate the physician self-referral law. However, the provision of such remuneration may implicate the anti-kickback statute. Similarly, donations by an entity that furnishes designated health services directly to a person or organization that is not a physician (or the immediate family member of a physician), such as a nonprofit organization or free or charitable clinic, would not create a direct compensation arrangement that implicates the physician self-referral law. However, if the recipient of the cybersecurity technology or services has a financial relationship with a physician, there would exist an unbroken chain of financial relationships that must be analyzed to determine whether there exists an indirect compensation arrangement that implicates the physician self-referral law.

F. Nonsubstantive Changes and Out-of-Scope Comments

1. Nonsubstantive Changes

We are making some nonsubstantive revisions to our regulation text for consistency with longstanding stated policy and to ensure conformity between the text of similar regulations (for example, changing ''can'' to ''may'' at § 411.357(d)(1)(ii) for conformity between the exceptions for personal service arrangements and limited remuneration to a physician). We are also updating language to reflect the agency's current lexicon (for example, changing ''through'' to ''under'' in paragraph (2) of the definition of ''designated health services'' at § 411.351). Finally, we made revisions to improve the grammar and clarity of certain regulations (for example, changing ''not including any designated health services'' to ''does not include any designated health services'' in the exception for assistance to compensate a nonphysician practitioner at § 411.357(x)(4)(ii)).

From time to time, changes in the conventions for regulations published in the Code of Federal Regulations necessitate nonsubstantive revisions of existing regulations. In this final rule, we are providing the entire text of §§ 411.351 through 411.357 to aid the regulated industry with compliance efforts. Because of this, we are taking the opportunity to update or include new citations to chapters, section, and paragraphs that are referenced in certain of our regulations in these sections. For example, we included precise paragraph references in § 411.357(t). In addition, we are including headers for certain paragraphs within our regulations, for example, § 411.354(d)(1) through (6).

2. Out-of-Scope Comments

We received several comments that are outside the scope of this rulemaking, for example, comments requesting revisions to the exception for in-office ancillary services, suggesting policy changes related to physician-owned hospitals, and making recommendations for statutory changes to section 1877 of the Act. In addition, some of the commenters described their interpretations of various physician self-referral issues or asked questions about existing regulations that are not included in this rulemaking.

We appreciate these commenters taking the time to present these issues; however, these comments are beyond the scope of this rulemaking and are not addressed in this final rule. The out-of-scope issues raised by these commenters may be addressed in future rulemaking. We express no view on these issues, and our silence should not be viewed as an affirmation of any commenter's interpretations or views.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-

day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires that we solicited comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Exceptions to the Physician Self-Referral Law Related to Compensation (§ 411.357)

We are finalizing new exceptions for compensation arrangements that facilitate value-based health care delivery and payment in a value-based enterprise (§ 411.357(aa)). A value-based enterprise is required to have a governing document that describes the enterprise and how its VBE participants intend to achieve the value-based purposes of that enterprise (*see* the definition of ''value-based enterprise'' at § 411.351). The exception for value-based arrangements with meaningful downside financial risk to the physician at § 411.357(aa)(2) requires a description of the nature and extent of the physician's downside financial risk to be set forth in writing. The exception for value-based arrangements at § 411.357(aa)(3) requires the arrangement to be set forth in writing and signed by the parties. All exceptions at § 411.357(aa) require records of the methodology for determining and the actual amount of remuneration paid under the arrangement to be maintained for a period of at least 6 years. We also added a new exception for cybersecurity technology and related services (§ 411.357(bb)), and arrangements under this new exception have to be documented in writing. Finally, we have streamlined the parties that must sign the writing in the exception for physician recruitment (§ 411.357(e)). The burden associated with writing and signature requirements is the time and effort necessary to prepare written documents and obtain signatures of the parties. The burden associated with record retention requirements is the time and effort necessary to compile and store the records.

While the writing, signature, and record retention requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons without federal regulation during the normal course of their activities. Specifically, we believe that, for normal business operations purposes, health care providers and suppliers document their financial arrangements with physicians and others and retain these documents in order to identify and be able to enforce the legal obligations of the parties. Therefore, we believe that the writing, signature and record retention requirements should be considered usual and customary business practices.

We did not receive any public comments regarding our position that the burden associated with these requirements is a usual and customary business practice that is exempt from the PRA.

IV. Regulatory Impact Statement (or Analysis) (RIA)

A. Statement of Need

This final rule aims to remove potential regulatory barriers to care coordination and value-based care created by the physician self-referral law. Currently, certain beneficial arrangements that would advance the transition to value-based care and the coordination of care among providers in both the Federal and commercial sectors may be impermissible under the physician self-referral law. Industry stakeholders have informed us that, because the consequences of noncompliance with the physician self-referral law are so dire, providers, suppliers, and physicians may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce global health system efficiencies, and lower costs (or slow their rate of growth). This final rule addresses this issue by establishing three new exceptions that protect certain arrangements for value-based activities between physicians and entities that furnish designated health services in a value-based enterprise. These exceptions provide enhanced flexibility for physicians and entities to innovate and work together while continuing to protect the integrity of the Medicare program.

Commenters on the CMS RFI told us that they currently invest sizeable resources to comply with the physician self-referral law's referral and billing prohibitions and avoid substantial penalties related to noncompliance with this and related laws, including the Federal False Claims Act. Commenters on the proposed rule echoed the significant cost burden of complying with the physician self-referral law. The proposals finalized in this final rule that do not directly address value-based arrangements seek to balance program integrity concerns against the stated considerable burden faced by the regulated industry. These finalized provisions reassess our regulations to ensure that they appropriately reflect the scope of the statute's reach, establish exceptions for common nonabusive compensation arrangements between physicians and the entities to which they refer Medicare beneficiaries for designated health services, and provide guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral law. We believe that these reforms will significantly reduce compliance burden by providing additional flexibility to enable parties to enter into nonabusive arrangements and by making physician self-referral law compliance more straightforward.

B. Overall Impact

1. Executive Orders and the Regulatory Flexibility Act

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule is considered to be economically significant. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as a major rule, as defined by 5 U.S.C. 804(2).

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. For purposes of the RFA, most hospitals and most other providers and suppliers are considered small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. We anticipate that a large portion of affected entities are small based on these standards. The specific affected entities are discussed later in this section. Individuals and states are not included in the definition of a ''small entity.'' HHS considers a rule to have a significant impact on a substantial number of small entities if it has an impact of at least three percent of revenue on at least five percent of small entities. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

We determined that this final rule does not have a significant impact on small businesses because it will likely reduce, not increase, regulatory burden. This final rule will not require existing compliant financial relationships to be restructured. Instead, it will provide important new flexibilities to enable parties to create new arrangements that advance the transition to a value-based health care system and remove regulatory barriers to certain beneficial and nonabusive arrangements, such as the donation of cybersecurity technology and services. It will also reduce burden by clarifying certain key provisions found in current regulations. Also, although we expect entities to incur costs, these costs are estimated to be less than $1,000 per entity. These costs are unlikely to have an impact of three percent of revenue, and we expect they will be offset by savings resulting from this rule. Overall, this final rule is accommodating to legitimate financial relationships while reducing regulatory burden and continuing to protect against program and patient abuse.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The impact of this rule on small rural hospitals is minimal. In fact, several provisions of the rule benefit small rural hospitals by giving them more flexibility to maintain operations and participate in innovative arrangements that enhance care coordination and advance the transition to a value-based health care system. Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $156 million. This rule imposes no mandates on state, local, or tribal governments, or on the private sector, and reduces regulatory burden on health care providers and suppliers.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule is a deregulatory action.

2. Expected Outcomes and Benefits

a. Value-Based Health Care Delivery and Payment

A 2019 study of 70 participants—including 62 health plans, seven Medicaid FFS states, and Traditional Medicare—accounting for nearly 226.5 million Americans, or 77 percent of the covered U.S. population, highlighted the continued move away from a FFS system that pays only on volume and towards value-based health care delivery and payment models.[32] The study showed that, in calendar year 2018, 39.1 percent of health care dollars were traditional FFS or other legacy payments not linked to quality, 25.1 percent of health care dollars were FFS payment linked to quality and value (described as pay-for-performance or care coordination fees), 30.7 percent of health care dollars were a composite of shared savings, shared risk, and bundled payments in alternative payment models built on a FFS architecture, and 5.1 percent of health care dollars were population-based payments (that is, capitation, global budget, or percent of premium payments).[33] Although the study showed that payors made the majority of 2018 payments on a FFS basis (or in models built on a FFS architecture), the 2018 payments represent a 4.6 percent decline in FFS payments not linked to quality from such payments in 2017 (from 41 percent in 2017 to 39.1 percent in 2018), and a 34.2 percent increase in population-based payments over such payments in 2017 (from 3.8 percent in 2017 to 5.1 percent in 2018).[34]

In sections I.B. and II.A.1. of this final rule, we described the current landscape of health care delivery and payment both within and outside the Medicare program. We explained that the application of the physician self-referral law to *all* financial relationships between entities and the physicians who refer to them (or the immediate family members of such physicians) has inhibited a more rapid advancement toward a health care system that pays for outcomes rather than procedures. Based on stakeholder responses to numerous CMS requests for information, including the CMS RFI that is part of the Department's Regulatory Sprint, we proposed regulatory revisions to address barriers to innovative care coordination and value-based health care delivery and payment (84 FR 55766). After considering the comments on the proposed rule, we are finalizing policies intended to facilitate the transition to value-based health care delivery and payment by permitting appropriate compensation arrangements

[32] APM Measurement: Progress of Alternative Payment Model; Health Care Payment Learning & Action Network, October 2019; *see https://hcp-lan.org/apm-measurement-effort/* and *http://hcp-lan.org/workproducts/apm-methodology-2019.pdf.*

[33] *Id.*

[34] *Id.*

that further the goals of a value-based system without posing a risk of program or patient abuse. Specifically, as described in section II.A. of this final rule, we designed and are finalizing new exceptions for value-based arrangements at final § 411.357(aa)—with safeguards intended to: (1) Protect against program or patient abuse that could lead to increased expenditures; and (2) maximize the potential of value-based care delivery and improved care coordination in reducing waste and program expenditures. The new exceptions are also applicable to those indirect compensation arrangements between an entity and a physician that involve a value-based arrangement to which the physician (or the physician organization in whose shoes the physician stands) is a direct party.

Although existing exceptions utilized by parties to protect financial relationships that exist outside of value-based health care delivery and payment systems also include safeguards designed to protect against program or patient abuse, they do not promote the potential for improvements in quality and reductions in expenditures the way that that the new exceptions set forth in this final rule may. By making available the new exceptions for value-based arrangements established in this final rule, we expect to achieve significant progress in reducing program expenditures without sacrificing program integrity. However, we are unable to quantify with certainty the overall net costs, including net expenditures of the Medicare program, related to changes in industry behavior that we can reasonably expect following the effective date of this final rule. Even so, we believe that our final policies are reasonably likely to permit, if not encourage, behavior that will reduce waste in the U.S. health care system, including Medicare and other Federal health programs, and that these changes will result in lower costs for both patients and payors, and generate other benefits, such as improved quality of patient care and lower compliance costs for providers and suppliers.

(1) Expectation of Value-Based Arrangements

As discussed in section II.A. of this final rule, compensation arrangements that qualify as value-based arrangements may take a variety of forms. Those that implicate the physician self-referral law will be directly or indirectly between an entity that furnishes designated health services and a physician who refers to that entity (or the immediate family member of a physician who refers to that entity). Although some compensation arrangements that qualify as value-based arrangements may satisfy the requirements of a ''traditional'' exception to the physician self-referral law, most do not. These include arrangements that: (1) Involve the provision of free or reduced cost items and services; (2) tie compensation to the ordering or furnishing of designated health services; (3) tie compensation to the refraining from ordering, delaying the order of, or furnishing designated health services; or (4) involve the sharing of profits or losses such that compensation does not directly relate to the items or services actually provided by a physician. Based on our experience administering the Shared Savings Program and Innovation Center models, information provided by commenters on the CMS RFI and the proposed rule (including payors that supported the establishment of the exceptions at final § 411.357(aa)), and information shared publicly by providers, suppliers, practitioners, health plans, and others, following the issuance of this final rule—and, specifically, once the exceptions at final § 411.357(aa) for value-based arrangements are available—we reasonably expect parties to enter into arrangements such as the following:

- Providing staff and other resources to physicians at below fair market value to help with patient education, pre-admission evaluations, and post-procedure follow-up and monitoring.
- Shared savings and shared loss arrangements under which the entity and the physician share financial risk for achievement of the value-based purpose(s) of the value-based enterprise or the outcome measures against which the recipient of the remuneration is assessed.
- Arrangements that enhance patient care by providing items at no cost to physicians. We note that an important piece of ensuring good outcomes and fewer complications is patient education. Hospitals are often better-positioned or willing to develop video or print materials to prepare surgical patients for what to expect pre- and post-surgery, but are not in direct contact with patients until the day of surgery. Under the new exceptions, hospitals could provide those materials at no charge to physicians for use in their practices, benefiting both hospitals and physicians, as well as surgical patients.
- Providing free telehealth equipment to physicians for use while treating patients in their office locations. The technology could be utilized for consults with a donor hospital to avoid unnecessary ambulance transports, ER visits, and exposing the patient to greater risk when emergencies or complications occur in the physician office, or could be used by primary care physicians to obtain immediate input from specialists while a patient is present in the primary care physician's office.
- Provision of data analytics services. A specialty physician practice (or other entity) may wish to provide free data analytic services to a primary care physician practice with which it works closely. The data analytics could, for example, identify practice patterns that deviate from evidence-based protocols or determine whether follow-up care recommended by the specialty physician practice is being sought by patients. In turn, the identification of deviant practice patterns and when follow up care is recommended could lead to better, more effective care for patients and reduced costs to Federal health care programs.

We cannot, however, predict the form of all potential value-based arrangements or which entities and physicians will enter into value-based arrangements and what form their specific arrangements will take. More specifically, based on comments submitted by stakeholders, our understanding of currently existing value-based arrangements and care coordination arrangements, and our assumption that there will be continued innovation, we expect significant heterogeneity in the arrangements for which the new exceptions at final § 411.357(aa) will be utilized.

(2) Potential Outcomes and Benefits of Value-Based Arrangements

As described above, we can reasonably predict that our final policies and the exceptions at final § 411.357(aa) will result in changes in stakeholder behavior. Entities and physicians may increase their participation in beneficial nonabusive value-based arrangements, including care coordination arrangements, that implicate the physician self-referral law. In this regard, and with respect to the intended outcomes and benefits related to this final rule, we anticipate that the policies in this final rule may: (1) Remove barriers to robust participation in value-based health care delivery and payment systems, including those administered by CMS and non-Federal payors; (2) facilitate arrangements for patient care coordination among affiliated and unaffiliated health care providers, practitioners, and suppliers; (3) provide certainty for participants in the Shared Savings Program that wish to establish compensation arrangements outside of

the Shared Savings Program similar to those among providers and suppliers in Shared Savings Program ACOs; and (4) provide certainty for participants in Innovation Center models that wish to continue compensation arrangements established while participating in an Innovation Center model following the model's conclusion or establish similar arrangements outside of the model. Associated benefits that we anticipate will arise from these intended outcomes are: (1) Better care coordination for patients, including Medicare beneficiaries, resulting in the reduction in costs to payors and patients from poorly coordinated, duplicative care; (2) improved quality of care and outcomes for patients, including Medicare beneficiaries; (3) substantial reduction in compliance costs to providers and suppliers to which the physician self-referral law's prohibitions apply; and (4) reduction in administrative complexity and related waste from continued progress toward interoperability of data and electronic health records.

(3) Cost Impact of Value-Based Arrangements

A. General

As noted above, we are unable to quantify with certainty the overall net costs, including net expenditures of the Medicare program, related to the changes in industry behavior that we can reasonably expect following the effective date of this final rule. However, based on the studies and reported experiences of payors, providers, suppliers, and patients that we discuss in this section IV.B. of this final rule, we believe that value-based arrangements such as those described in section IV.B.2.a.(1). of this final rule have great potential to reduce waste in the U.S. health care system, lower costs for both patients and payors, and generate other benefits such as improved quality of patient care and lower compliance costs for providers and suppliers.

A recent review of literature from January 2012 to May 2019 focusing on unnecessary spending, or waste, in the U.S. health care system (2019 Waste in U.S. Health Care Study) indicates that waste related to the failure of care coordination alone results in annual costs of $27 billion to $78 billion.[35] Much of the research on waste and improvement reviewed in the 2019 Waste in U.S. Health Care Study was conducted in Medicare populations. The 2019 Waste in U.S. Health Care Study noted compelling empirical evidence that interventions, such as aligning payment models with value or supporting delivery reform to enhance care coordination, safety, and value, can produce meaningful savings and reduce waste by as much as half. The 2019 Waste in U.S. Health Care Study also identified waste from administrative complexity (resulting from fragmentation in the health care system) as the greatest contributor to waste in the U.S. health care system at an estimated $266 billion annually, and highlighted the opportunity to reduce waste in this category from enhanced payor collaboration with health care providers and clinicians in the form of value-based payment models. According to the 2019 Waste in U.S. Health Care Study, as value-based care continues to evolve, there is reason to believe that such interventions can be coordinated and scaled to produce better care at lower cost for all U.S. residents. Moreover, in value-based arrangements, improvements could reduce waste related to overtreatment and low-value care, a separate category of waste in the U.S. health care system. Other recently published peer-reviewed articles also suggest that value-based arrangements can reduce costs.[36]

A case study targeted at determining the specific factors that reduce Medicare payments and lead to hospital savings in bundled payment models for lower extremity joint replacement surgeries (which provide a lump sum payment to be shared among providers for an episode of care instead of payment for every service performed) in one Texas health system found that, between July 2008 and June 2015, the system's five hospitals were able to reduce total Medicare spending per episode of care by $5,577, or 20.8 percent, in cases without complications, and by $5,321, or 13.8 percent, in cases with complications.[37] The hospitals also recognized $6.1 million in internal cost savings, along with slight decreases in emergency room visits and readmission rates, and a decrease in cases with a prolonged length-of-stay admission. Over half of the internal cost savings were attributable to reduced implant costs.[38] We note that the product standardization incentive programs that contribute to such internal cost savings involve compensation arrangements between hospitals and physicians which, depending on their structure, may not satisfy the requirements of any current exceptions to the physician self-referral law, but to which the new exceptions for value-based arrangements apply. Relatedly, in 2018, a large health plan announced that it was expanding a bundled payment program for spinal surgeries and hip/knee replacements to new markets, after finding savings of $18,000 per procedure,[39] and a health network reported over $10 million in savings in 2017 with more anticipated savings in 2018.[40]

B. Medicare Expenditures

We cannot predict with certainty how many and which parties will avail themselves of the new and revised exceptions or the changes in provider and supplier behaviors that could result. Influence on provider and supplier behavior could either reduce or increase overall program spending, although the literature described in this section IV.B.2. of this final rule indicates great potential for waste reduction and cost savings across the U.S. health care system, including the Medicare program. We note that any short-term increase in expenditures could result

[35] William H. Shrank, MD, MSHS, et al., *Waste in the U.S. Health Care System, Estimated Costs and Potential for Savings,* 322(15) Journal of the American Medical Association 1501 (2019), available at *https://jamanetwork.com/journals/jama/fullarticle/2752664.*

[36] Brian W. Powers, et al., *Impact of Complex Care Management on Spending and Utilization for High-Need, High-Cost Medicaid Patients,* American Journal of Managed Care, 26(2), e57–e63 (Feb. 2020), *available at https://doi.org/10.37765/ajmc.2020.42402* (a study of a complex care management program implemented in Tennessee for high-need, high-cost Medicaid patients, which found that the program reduced total medical expenditures by 37 percent and inpatient utilization by 59 percent); and Shreya Kangovi, et al., *Evidence-Based Community Health Worker Program Addresses Unmet Social Needs and Generates Positive Return on Investment,* Health Affairs, 39(2), 207–13 (Feb. 2020), *available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.00981* (a study that found that every dollar invested in the Individualized Management for Patient-Centered Targets (IMPaCT) intervention, which is ''a standardized community health worker intervention that addresses socioeconomic and behavioral barriers to health in low-income populations,'' yielded a return of $2.47 from the perspective of a Medicaid payer. This return was realized within a single fiscal year).

[37] Amol Navathe, et al., *Cost of Joint Replacement Using Bundled Payment Models, JAMA Intern Med.* 2017;177(2):214–222. doi:10.1001/jamainternmed.2016.8263, *available at https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2594805.*

[38] *See* Vera Gruessner, *3 Ways Bundled Payment Models Brought Hospital Cost Savings Down,* Health Payer Intelligence (Jan. 2017), *available at https://healthpayerintelligence.com/news/3-ways-bundled-payment-models-brought-hospital-cost-savings.*

[39] *See* David Muhlestein, et al., *Recent Progress in the Value Journey: Growth of ACOs and Value-Based Payment Models in 2018,* Health Affairs (Aug. 2018) *available at https://www.healthaffairs.org/do/10.1377/hblog20180810.481968/full/.*

[40] *See* Shane Wolverton, *Providers Partner with Payers for Bundled Payments,* Becker's Hospital Review (May 2018), *available at https://www.beckershospitalreview.com/payer-issues/providers-partner-with-payers-for-bundled-payments.html.*

from appropriate utilization of services as patients seek and accept medically indicated care that they may have forgone in the absence of care coordination efforts and value-based arrangements for which exceptions were previously unavailable, and that appropriate utilization could prevent greater expenditures and other negative results to life over the longer term. Because of this uncertainty, we cannot quantify any impact on Medicare expenditures. We are confident that the regulations established or revised in this final rule include sufficient and appropriate safeguards to protect against program or patient abuse, including inappropriate utilization due to a physician's financial self-interest. We believe that our final policies fall squarely within the Secretary's authority under section 1877(b)(4) of the Act to establish exceptions for financial relationships that do not pose a risk of program or patient abuse and, therefore, anticipate no increased spending due to inappropriate utilization. We will continue to assess the impact of our final policies on program expenditures. As noted in more detail later in this RIA, our view of the beneficial anticipated effects that will result from the policies in this final rule remains largely unchanged from the proposed rule.

As noted above, we are not able to provide quantitative estimates of overall savings to or expenditures of the Medicare program that will result from this final rule. However, with respect to parties currently participating in the Shared Savings Program and Innovation Center models, we have determined that this final rule would not significantly alter the conditions upon which such providers and suppliers operate. Although we do not know which new value-based models or programs will be implemented in the future, such programs and models will be associated with an estimated impact *at the time they are implemented.* Thus, we have determined that the policies set forth in this final rule will have no impact with regard to Medicare expenditures under the Shared Savings Program and Innovation Center models.

C. Commercial Sector and Other Federal Payors

A recent survey of over 100 commercial payors showed that, in 2018, ''pure FFS'' payment—where each medical service is billed and paid for separately—accounts for only 37.2 percent of commercial payor reimbursement, and is expected to drop to 26 percent by 2021.[41] According to the payors surveyed, payors that adopted value-based health care delivery and payment models reduced health care costs by an average of 5.6 percent, improved provider collaboration, and created more impactful member engagement. Although we cannot make any quantitative estimates regarding cost savings or expenditures that may result from this final rule, we are aware of the success of certain innovative value-based arrangements that resulted in cost savings for third-party payors, improvements in quality of care, or both. The reported success of some of these programs exemplifies the promising nature of value-based health care delivery and payment.

There are numerous reported examples of successful value-based health care delivery and payment programs developed and implemented by commercial health plans. For example, one health plan recently reported that it saved $1 billion through avoided costs in 3 years of its recent primary care pay-for-value program that offers primary care practices rewards for their performance on quality, cost, and utilization measures, while also improving outcomes for its members.[42] According to this health plan, members treated by a primary care provider in the program had 11 percent fewer emergency room visits in 2017 than members treated by a primary care physician not in the program. The health plan also stated that members with a primary care physician in the program experienced 16 percent fewer inpatient admissions in 2017 compared to members seeing a primary care physician not in the program, potentially saving the health plan $224 million in inpatient care costs.[43]

A collaboration between a physician-led ACO and a health plan in North Carolina similarly reduced costs while improving quality of care.[44] Specifically, a June 2020 study concluded that the 47 primary care practices that participated in the collaboration: (1) Reduced the total cost of care by 4.7 percent for commercial patients; (2) reduced the total cost of care by 6.1 percent for Medicare Advantage patients; and (3) improved their Medicare star ratings, on average, from 3 to 4.5 stars. Another study, in 2020, by a different health plan analyzed the plan's Medicare Advantage enrollees and network primary care physician practices. This health plan determined that primary care physicians paid under global capitation improved certain patient outcomes related to preventive care and chronic conditions, such as higher screening rates for colorectal and breast cancer, higher rates of medication review, and higher controlled blood sugar levels.[45]

There are also studies that suggest that improved care coordination may decrease costs and enhance health outcomes. One randomized, controlled trial evaluated the cost-effectiveness of a home-based care coordination program that targeted older adults with problems self-managing their chronic illnesses.[46] Study participants in the test group received care coordination services from a nurse. They also received a pill organizer. The results of this study showed that, for those beneficiaries who participated in the study for more than 3 months, total Medicare costs were $491 lower per month than in the control group. Another study conducted by the Centers for Disease Control demonstrated that certain interventions, such as team-based or coordinated care, increase patient medication adherence rates.[47]

[41] *Finding the Value in Value-Based Care: The State of Value-Based Care in 2018;* a Signature Research Report commissioned by Change Healthcare (June 2018); *see also,* Thomas Beaton, *Value-Based Payment Adoption Drives 5.6% Reduction in Care Costs,* Health Payer Intelligence (June 2018) *available at https://healthpayerintelligence.com/news/value-based-payment-adoption-drives-5.6-reduction-in-care-costs.*

[42] *See* Press Release, Highmark, Inc., *Highmark saves more than $1 billion in avoided cost with True Performance program* (Oct. 5, 2020), *available at https://www.highmark.com/newsroom/press-releases.html#!release/highmark-saves-more-than-1-billion-in-avoided-cost-with-true-performance-program.*

[43] *See* Press Release, Highmark, Inc., *Highmark's True Performance Program Avoided Health Care Costs by More Than $260 Million in 2017* (June 26, 2018), *available at https://www.highmark.com/newsroom/press-releases.html#!release/highmarks-true-performance-program-avoided-health-care-costs-by-more-than-260-million-in-2017.*

[44] *See* Press Release, Blue Cross and Blue Shield of North Carolina, *Primary Care ACOs from Blue Cross NC and Aledade Show Significant Savings and Quality Improvements* (July 20, 2020), *available at https://mediacenter.bcbsnc.com/news/primary-care-acos-from-blue-cross-nc-and-aledade-show-significant-savings-and-quality-improvements.*

[45] *See* Press Release, UnitedHealth Group, *Physicians Provide Higher Quality Care Under Set Monthly Payments Instead of Being Paid Per Service, UnitedHealth Group Study Shows* (Aug. 11, 2020), *available at https://www.unitedhealthgroup.com/newsroom/2020/uhg-study-shows-higher-quality-care-under-set-monthly-payments-403552.html.*

[46] Karen Dorman Marek et al., *Cost analysis of a home-based nurse care coordination program,* J. Am. Geriatr. Soc. 2014;62(12):2369–2376.

[47] Andrea B. Neiman, et al., *CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management — Innovations and Opportunities,* 66 Weekly 45 (Nov. 17, 2017),

Continued

Specifically, in a 2015 study, patients assigned to team-based care—including pharmacist-led medication reconciliation and tailoring, pharmacist-led patient education, collaborative care between pharmacist and primary care provider or cardiologist, and two types of voice messaging—were significantly more adherent with their medication regimen 12 months after hospital discharge (89 percent) compared with patients not receiving team-based care (74 percent).

D. Conclusion

We believe that the experience of the payors and organizations described in this section IV.B.2. of this final rule highlight the potential for eliminating a significant amount of unnecessary expenditures (waste) in the U.S. health care system, including in the Medicare program. As noted earlier, the 2019 Waste in U.S. Health Care Study indicates annual costs of $27 billion to $78 billion from the failure of care coordination alone.[48] This study identified $266 billion in annual costs from administrative complexity in the furnishing of care and compliance with laws and regulations. We cannot predict with absolute certainty whether value-based arrangements that parties enter into as a result of our final policies will reduce these annual costs, but we believe that it is likely that innovative value-based arrangements and payment for value-based health care delivery will continue to achieve the results described above in this section IV.B.2. We are also unable to provide quantitative estimates of the impact on costs that such arrangements will have. However, we believe there is great potential for reducing the expense of waste in the U.S. health care system through improved care coordination and reduced administrative complexity.

b. Clarifying Revisions and New Exceptions for Nonabusive Financial Relationships

(1) Key Terminology, the Application and Scope of the Physician Self-Referral Law, and New Exception for Limited Remuneration to a Physician

A. Summary of the Final Regulations

In addition to the final regulations discussed in subsections 2.a. and 2.b.(2). of this section IV.B., this final rule revises numerous current regulations and establishes new regulations, including a new exception at final § 411.357(z) for limited remuneration to a physician, intended to clarify the scope of the prohibitions of the physician self-referral law and simplify compliance with the exceptions to the law's referral and billing prohibitions. To this end, this final rule: (1) Establishes a definition of the term ''commercially reasonable'' at § 411.351; (2) establishes special rules at § 411.354(d)(5) and (6) that identify the universe of compensation formulas that are considered to be determined in a manner that takes into account the volume or value of a physician's referrals or the other business generated by a physician; (3) revises the definition of ''fair market value'' at § 411.351; (4) clarifies CMS policy regarding the permissible methodologies for distributing profits from designated health services within a group practice; (5) clarifies CMS policy regarding compensation formulas that will be deemed not to directly take into account the referrals of a physician in a group practice; (6) recognizes the independent obligation to comply with the anti-kickback statute and governmental billing and claims submission rules by removing from most exceptions to the physician self-referral law the requirements that the financial relationship between the entity and the physician (or immediate family member of the physician) does not violate the anti-kickback statute and does not violate any Federal or state law or regulation governing billing or claims submission; (7) revises the definition of ''designated health services'' at § 411.351 to, in effect, remove inpatient hospital services ordered after a patient's admission to the hospital when such services are ordered by a physician who is not the physician who made the referral for the inpatient admission; (8) revises the definition of ''physician'' at § 411.351 to limit the physician referrals to which the law's prohibitions apply to only those physicians who qualify as a ''physician'' under section 1861(r) of the Act; (9) revises the definition of ''remuneration'' at § 411.351 to clarify that the provision of certain items, devices, and supplies from an entity to a referring physician does not establish a compensation arrangement when those items, devices, or supplies are, in fact, used solely by the physician for the purpose(s) established in the statute and regulation; (10) revises the definition of ''transaction'' and establishes a new definition of ''isolated financial transaction'' at § 411.351 to clarify CMS policy regarding the types of compensation arrangements to which the exception at § 411.357(f) is applicable; (11) alleviates confusion reported by stakeholders regarding the period of disallowance for referrals and billing following a violation of the physician self-referral law; (12) permits parties to reconcile payment discrepancies in compensation arrangements without running afoul of the physician self-referral law; (13) removes certain interests held by a physician from qualifying as an ownership or investment interest that implicates the physician self-referral law; (14) clarifies when compensation is considered to be ''set in advance'' for purposes of satisfying the requirements of the exceptions to the physician self-referral law; (15) revises CMS policy regarding modifications to the financial terms of a compensation arrangement to eliminate specific timeframe limitations for such modifications; (16) clarifies CMS policy regarding the circumstances under which an entity may direct a physician's referrals to a particular provider, practitioner, or supplier; (17) expressly prohibits an entity from conditioning the existence of a compensation arrangement or the amount of a physician's compensation on the number or value of the physician's referrals to a particular provider, practitioner, or supplier; (18) clarifies that required signatures may be electronic or in any other form that is valid under applicable Federal or state law; (19) allows parties 90 consecutive calendar days to obtain documentation necessary to satisfy the writing requirement of an applicable exception; (20) clarifies the requirement for exclusive use of office space or equipment under the exceptions at § 411.357(a) and (b); (21) clarifies the circumstances under which a physician practice must sign the documentation of a recruitment arrangement between a hospital and a physician; (22) clarifies and expands the application of the exception at § 411.357(i) for payments by a physician (or immediate family member of a physician) to an entity; (23) expands the application of the exception at § 411.357(l) to fair market value payments for the rental of office space, even where the duration of the arrangement is less than 1 year; (24) makes permanent the EHR exception; (25) clarifies the scope of the EHR exception to permit donations of cybersecurity software and services that are necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records; (26) allows for flexible scheduling of physician contribution payments for electronic health records items and services following the initial donation of

available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm.

[48] William H. Shrank, MD, MSHS, et al., *Waste in the U.S. Health Care System, Estimated Costs and Potential for Savings.*

such items and services; (27) permits donations of replacement electronic health records items and services, even if the physician already possesses equivalent items or services; (28) clarifies timing issues related to arrangements between a physician and NPP where the physician receives assistance from a hospital to compensate the NPP; (29) updates and eliminates out-of-date references to bolster clarity of the scope and application of the physician self-referral regulations; (30) establishes a new exception for limited remuneration to a physician that does not require contemporaneous documentation of the terms of the arrangement or that the compensation is set in advance of the provision of the physician's services; and (31) modifies other exceptions that apply to arrangements for the personal services of physicians to ensure applicability on a going-forward basis following the commencement of an arrangement that satisfies the requirements of the new exception for limited remuneration to a physician.

B. Expectation of Industry Behavior

Following the effective date of our final policies, we anticipate a reduction in disclosures to the SRDP of potential or actual violations of the physician self-referral law because stakeholders will have a clearer understanding of the scope and application of the physician self-referral law, as well as CMS' interpretation of the law's provisions. We anticipate that entities will continue to provide electronic health records items and services to physicians with the same scope and frequency as the industry has observed since the issuance of the EHR exception in 2006. We also anticipate that parties that made submissions to the SRDP that have not yet been settled may withdraw all or portions of their disclosures, similar to what occurred following clarifications of physician self-referral policies in the CY 2016 PFS final rule. Although we expect that entities will utilize the new exception at § 411.357(z) for limited remuneration to a physician, as explained in section II.E.1. of this final rule, we anticipate that the exception's greatest utility will come during retrospective review of compliance with the physician self-referral law. As we noted in section III.A. of this final rule, we believe that, for normal business operations purposes, entities document their financial arrangements with physicians and others in order to identify and be able to enforce the legal obligations of the parties. Thus, we believe that the exception will be utilized more often by parties that did not fully document an arrangement in writing or set compensation in advance than by parties that affirmatively choose not to document their arrangement in writing or set physician compensation in advance when developing a new arrangement for physician services. Finally, we anticipate that some physician practices will revise their compensation methodologies with respect to the distribution of profits from designated health services furnished by the group in order to ensure compliance with the clarifying regulations at § 411.352(i) that become effective January 1, 2022 and continued qualification as a ''group practice'' under the regulations at § 411.352.

C. Potential Outcomes, Benefits, and Costs of Final Policies Related to Key Terminology, the Application and Scope of the Physician Self-Referral Law, and New Exception for Limited Remuneration to a Physician

According to commenters, one of the most significant benefits of this final rule is the establishing of clear boundaries for parties in setting the financial terms of compensation arrangements that do not qualify as value-based arrangements. We are unable to quantify with certainty the impact of our clarifications, expanded flexibilities, and the new exception at final § 411.357(z) on costs to the regulated industry; however, we believe that most entities that have financial relationships with physicians to which the physician self-referral law applies will see some level of reduced expenditures.

Many of the entities whose financial relationships with physicians are subject to the requirements of the physician self-referral law are hospitals and physician groups. An October 2017 study of 190 hospitals in 31 states across the United States revealed that an average community hospital (defined as 161 beds) annually dedicates 2.3 full-time equivalent employees to, and spends almost $350,000 on, compliance with Federal fraud and abuse laws, defined in the study as including the physician self-referral law, the anti-kickback statute, and laws and protocols requiring returning overpayments.[49] This study affirms commenter statements included in a 2015 Senate Finance Committee report that noted the high cost and difficulty of complying with the physician self-referral law.[50] We expect that the clarifications and regulatory revisions of this final rule will significantly reduce the costs to the regulated industry. (See section IV.C. of this final rule for further discussion of this study and the anticipated effects of this final rule on the burden identified in the study.)

CMS publishes aggregate SRDP settlement data on its website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements*. To date, we have received over 1200 disclosures to the SRDP. As of December 31, 2019, we have settled 335 disclosures by collecting an aggregate of $31.8 million from disclosing parties. Although we cannot estimate the number of compensation arrangements included in the pending disclosures that would be affected by the clarifications in this final rule, it is our observation that a substantial portion of the conduct already settled through the SRDP involved the failure of a compensation arrangement to satisfy the writing or signature requirements of an applicable exception, with many of those failures lasting for only a short period of time. Many disclosures involved the disclosing party's incorrect interpretation or misapplication of the physician self-referral law or CMS policy. Therefore, we believe that the clarifications in this final rule will reduce the perceived need for disclosure to the SRDP and allow parties to avoid the costs—including costs of compliance professionals, attorneys, market valuation experts, and accountants—of preparing and submitting a disclosure to the SRDP. As noted above, we also expect that some entities may withdraw a portion of or their entire SRDP disclosures following the issuance of this final rule. However, we are unable to quantify the avoidance of costs to the industry related to refraining from or withdrawing disclosures. We note that recoveries from SRDP settlements may also diminish, but this does not represent a cost to the Medicare program or trust fund. Where there is no violation of the physician self-referral law's referral and billing prohibitions, there is no refund due to the government under section 1877(g) of the Act for Medicare payments made to the entity.

[49] American Hospital Association, *Regulatory Overload: Assessing the Regulatory Burden on Health Systems, Hospitals and Post-Acute Care Providers* (October 2017), *available at https://www.aha.org/sites/default/files/regulatory-overload-report.pdf.*

[50] Senate Finance Committee Majority Staff Report, *Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovated Payment Models* (2015), *available at https://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf.*

Finally, we believe that the clarifications and revisions to the EHR exception, and the permanency of the exception, will facilitate the continued adoption and use of electronic health records, especially in small physician practices, by making permanent the exception for the donation of such items and services.

(2) New Exception for Cybersecurity Items and Services

The average breached health care organization faces $8 million dollars in costs as a result of the breach, or $400 per patient record involved.[51] One hospital reported spending $10 million to recover from a cyberattack, instead of paying a $30,000 ransom demanded by hackers,[52] while another hospital paid a $55,000 ransom to hackers, despite having backup copies of the affected files.[53] A cyberattack on a hospital in Germany is the suspected cause of the death of at least one patient.[54] A September 2020 cyberattack on a large health care system in the United States affected nearly 400 facilities, causing hospitals to divert ambulances during the initial stages of the attack.[55] In addition, staff reported that some lab test results were delayed. The system responded by suspending user access to its information technology applications related to operations across the United States, requiring the use of back-up processes, including paper medical record charting and labeling medications by hand, for nearly three weeks.

According to the Health Sector Cybersecurity Coordination Center (HC3), health care organizations should consider implementing strong risk management practices to help prevent data breaches and minimize any disruptions or loss if a breach occurs.[56] HC3 highlights that adequate prevention and preparation for data breaches will protect patients, minimize direct and indirect costs, and allow for more efficient operations of a health care organization.[57] Separately, the HCIC Task Force's 2017 report, among other things, highlighted its review of many concerns related to potential constraints imposed by the physician self-referral law and the Federal anti-kickback Statute. The report encouraged the Congress to evaluate an amendment to these laws specifically for cybersecurity software that would allow health care organizations the ability to assist physicians in the acquisition of this technology, through either donation or subsidy.[58] The HCIC Task Force noted that the existing regulatory exception to the physician self-referral law (§ 411.357(w)) and the safe harbor to the Federal anti-kickback statute (42 CFR 1001.952(y)) applicable to certain donations of EHR items and services could serve as a perfect template for an analogous cybersecurity provision.[59] In 2018, the American Medical Association surveyed over 1,300 physicians in a cybersecurity-related survey. Approximately 83 percent of the participants reported having experienced some sort of cybersecurity attack.[60] The study also highlighted that 50 percent of the surveyed physicians wished they could receive donations of security-related hardware and software from other providers, and recommended that we develop an exception to permit it.

As described in section II.E.2 of this final rule, we received overwhelming support from across the health care industry in response to our proposal to establish the new exception for cybersecurity items and services, and we anticipate significant expansion of cybersecurity efforts through donations following the effective date of this final rule, similar to the expanded adoption of EHR items and services reported by stakeholders following the establishment of the EHR exception in 2006. Support for the new cybersecurity exception came from many well-resourced organizations that are potential future donors of cybersecurity technology, such as health plans and large health systems, as well as from likely recipients of donations and trade groups representing practitioners. (We note that not all of the potential donors and recipients are entities and physicians to which the physician self-referral law applies.) Because of the cost of cybersecurity attacks to organizations that wish to donate or receive cybersecurity technology and services, and the general support among donors and recipients for the new cybersecurity exception, we anticipate significant investment in improvements to the cybersecurity hygiene of the health care industry. An organization's cybersecurity posture is only as strong as its weakest link, including weaknesses of downstream providers, suppliers, and practitioners that wish to receive donations; thus, donors are incented to protect themselves by donating cybersecurity technology and services that improves their cybersecurity.

We expect that the flexibilities afforded by the cybersecurity exception will facilitate the enhancement of protection against the corruption of or access to health records and other information essential to the safe and effective delivery of health care, as well as reduce the impacts of cybersecurity attacks, including the improper disclosure of PHI. This could ultimately reduce overall costs associated with cybersecurity attacks, including ransom payments, costs to patients whose PHI is improperly disclosed, and costs to providers and suppliers to reestablish cybersecurity. However, there are a variety of factors integral to determining the extent of the impact of the cybersecurity exception on the cybersecurity hygiene of the health care industry that remain too speculative to support a quantitative estimate of the impact of this final rule. For example, we cannot predict with certainty: (1) How many entities or physicians will

[51] *See* Health Sector Cybersecurity Coordination Center, *A Cost Analysis of Healthcare Sector Data Breaches* (Apr. 4, 2019), *available at https://www.hhs.gov/sites/default/files/cost-analysis-of-healthcare-sector-data-breaches.pdf.*

[52] *See* Naveen Goud, *ECMC Spends $10 Million to Recover from a Cyberattack,* Cybersecurity Insiders, *available at https://www.cybersecurity-insiders.com/ecmc-spends-10-million-to-recover-from-a-cyber-attack/.*

[53] *See* Samm Quinn, *Hospital pays $55,000 Ransom; No Patient Data Stolen,* Greenfield Daily Reporter (Jan. 15, 2018), *available at http://www.greenfieldreporter.com/2018/01/16/01162018dr_hancock_health_pays_ransom/.*

[54] *See* Patrick Howell O'Neill, *A patient has Died After Ransomware Hackers Hit a German Hospital,* MIT Technology Review (Sept. 18, 2020), *available at https://www.technologyreview.com/2020/09/18/1008582/a-patient-has-died-after-ransomware-hackers-hit-a-german-hospital/.*

[55] *See* Jeff Lagasse, *Universal Health Services Hit with Cyberattack that Shuts Down IT Systems,* Healthcare Finance (Sept. 2020), *available at https://www.healthcarefinancenews.com/news/universal-health-services-hit-cyberattack-shuts-down-it-systems-1*; Jessica Davis, *UHS Health System Confirms all US Sites Affected by Ransomware Attack,* Health IT Security (Oct. 2020), *available at https://healthitsecurity.com/news/uhs-health-system-confirms-all-us-sites-affected-by-ransomware-attack*; Jessica Davis, *3 Weeks After Ransomware Attack, All 400 UHS Systems Back Online,* Health IT Security (Oct. 2020), *available at https://healthitsecurity.com/news/3-weeks-after-ransomware-attack-all-400-uhs-systems-back-online*; and Press Release, Universal Health Services, *Statement from Universal Health Services* (Oct. 29, 2020), *available at https://www.uhsinc.com/statement-from-universal-health-services/.*

[56] *See* Health Sector Cybersecurity Coordination Center, *A Cost Analysis of Healthcare Sector Data Breaches.*

[57] *Id.*

[58] *See* HCIC Task Force Report, *available at https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.*

[59] *Id.*

[60] *See* American Medical Association, *Tackling Cyber Threats in Healthcare, available at https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/medical-cybersecurity-findings.pdf* and *https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/infographic-medical-cybersecurity.pdf.*

donate cybersecurity technology or services for which the parties may seek protection under the cybersecurity exception; (2) how such donations will improve the cybersecurity hygiene of recipients, donors, and the health care ecosystem as a whole; or (3) external factors—such as other policies promoting cybersecurity within the health care industry, how hackers will proliferate and develop new hacking strategies, or how cyberattack recovery costs and ransom costs will change—that could enable or hinder improved cybersecurity hygiene and potentially result in increased or decreased costs associated with cyberattacks. Thus, we cannot predict the specific quantitative impact of the flexibility afforded by the new cybersecurity exception on the costs or benefits to the Medicare program, or other Federal health care programs, beneficiaries, or the health care industry as a whole. Nonetheless, we expect that the flexibility to donate cybersecurity technology and services will benefit the health care ecosystem as a whole, improve cybersecurity across the industry, and reduce costs associated with cyberattacks (by reducing successful cyberattacks, and consequently, ransom fees and recovery costs).

3. Comment and Response

We sought comment on the economic impact of this final rule, including any potential increase or decrease in utilization, any potential effects due to behavioral changes, or any other potential cost savings or expenses to the Government as a result of this rule.

We received the following comment and our response follows.

Comment: One commenter requested that we provide detailed estimates of changes in Medicare program spending that CMS expects to result from the proposed new exceptions and other regulatory changes. The commenter asserted that certain successful value-based programs produce limited savings and many value-based programs produce no savings or even increase spending.

Response: We are unable to provide the detailed estimates requested by the commenter. It is impossible for CMS to provide quantitative estimates of savings to or expenditures of the Medicare program that will result from the establishment of the new exceptions at § 411.357(z), (aa), or (bb), or from clarification of key terms integral to the physician self-referral law and other regulatory revisions. However, we emphasize that we engaged in the Regulatory Sprint to facilitate the transition to value-based health care delivery and payment and realize the potential cost savings that come from improved quality and care coordination. Although we cannot estimate the precise dollar amount of impact, as described throughout this section IV.B.2. of this final rule, the potential for reduced program expenditures is significant, and the policies set forth in this final rule are intended to maximize this potential.

C. Anticipated Effects

This final rule will affect entities that furnish designated health services payable by Medicare and the physicians with whom they have financial relationships. The following items or services are designated health services: (1) Clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) outpatient speech-language pathology services; (5) radiology and certain other imaging services; (6) radiation therapy services and supplies; (7) durable medical equipment and supplies; (8) parenteral and enteral nutrients, equipment, and supplies; (9) prosthetics, orthotics, and prosthetic devices and supplies; (10) home health services; (11) outpatient prescription drugs; and (12) inpatient and outpatient hospital services. We do not have data on the number of entities and physicians that have financial relationships, but we believe a substantial fraction of Medicare-enrolled physicians, group practices, hospitals, clinical laboratories, and home health agencies are affected by the physician self-referral law. We anticipate that this final rule will have significant, ongoing benefits for the affected physicians and entities and the entire health care system.

To estimate the number of entities directly affected by this rule, we use Medicare enrollment data. According to this data, there were 2,265 single or multispecialty clinics or group practices, 3,159 clinical laboratories (billing independently), 2,016 outpatient physical therapy/speech pathology providers, 2,739 independent diagnostic testing facilities, 11,317 home health agencies, 6,072 inpatient hospitals, 4,402 rural health clinics, 172 comprehensive outpatient rehabilitation facilities, 8,836 federally qualified health centers, and 9,403 medical supply companies enrolled in Medicare in 2018.[61] In addition, we estimate that 400 physician practices unassociated with single or multispecialty clinics or group practices will independently review this final rule. We requested public comment on the entities affected by the rule.

We anticipate that directly affected entities will review this final rule in order to determine whether to explore newly permissible value-based arrangements and to take advantage of burden-reducing clarifications provided by the rule. We estimate that all directly affected entities described above that will be eligible to use the final rule will review the rule. In the proposed rule, we estimated that reviewing the final rule would require an average of 3 hours of time each from the equivalent of a compliance officer and a lawyer (84 FR 55837). The final rule responds to numerous comments received on the proposals discussed in the proposed rule, and includes significantly more information than the proposed rule. Although we did not receive any comments on our proposed estimate of three hours, in light of the increase in length from the proposed rule to the final rule, we have adjusted our estimate for the time required to review the final rule. We estimate that reviewing the final rule will require an average of 6 hours of time each from the equivalent of a compliance officer and a lawyer, and note that parties may review only the portions of the final rule that are applicable to their specific circumstances and needs. For example, parties that do not wish to participate in value-based health care and delivery at this time may not review sections I.B. and II.A. of this final rule.

To estimate the costs associated with this review, we use a 2019 wage rate of $35.03 for compliance officers and $69.86 for lawyers from the Bureau of Labor Statistics,[62] and we double those wages to account for overhead and benefits. As a result, we estimate total regulatory review costs of $64 million in the first year following publication of the final rule. We sought public comment on these assumptions.

In developing this final rule, we took great care to ensure that the safeguards against program and patient abuse in our new exceptions impose the minimum burden possible while providing robust protection against improper utilization and other harms against which the physician self-referral law is designed to protect. For example, we believe a value-based enterprise would ordinarily develop a governing document that describes the value-based

[61] CMS Program Statistics, *https://www.cms.gov/research-statistics-data-systems/cms-program-statistics/2018-medicare-providers.*

[62] U.S. Department of Labor, Bureau of Labor Statistics, May 2019 National Occupational Employment and Wage Estimates United States, *https://www.bls.gov/oes/current/oes_nat.htm.*

enterprise and how the VBE participants intend to achieve its value-based purpose(s), so our requirement does not impose any additional burden beyond what we anticipate parties would ordinarily develop. We also believe that parties to an arrangement under which remuneration is paid already keep business records necessary for a variety of purposes, such as income tax filings, records of compliance with state laws (including fee splitting laws), and, for nonprofit entities, justification of tax-exempt status. Therefore, we do not believe the requirement to maintain records of the methodology for determining and the actual amount of remuneration paid under a value-based arrangement for a period of at least 6 years imposes additional burden. In addition, we believe that physicians and entities routinely document their financial arrangements in writing as a common good business practice so that arrangements can be enforced. For example, we believe that an entity would ordinarily ensure that the details of a shared loss repayment agreement are documented in writing to ensure that the arrangement can be enforced under state law. Similarly, we believe that entities working together to achieve a purpose would routinely monitor their operations to confirm that their plans are working as intended. We sought comments on these assumptions.

The new exceptions for arrangements intended to facilitate the transition to value-based health care delivery and payment have numerous potential benefits that will reduce costs and improve quality, not only for Medicare and its beneficiaries, but for patients and the health care system in general. For example, the final exceptions provide important new flexibility for physicians and entities to work together to improve patient care and reduce costs. This increased flexibility will provide new opportunities for the private sector to develop and implement cost-saving, quality-improving programs that previously may have been impermissible. We anticipate that implementation of improvements and efficiencies, such as care redesign protocols resulting from private sector innovation, could have a beneficial effect on the care provided to Medicare beneficiaries and thereby result in savings for beneficiaries and the Trust Funds. We believe that these new exceptions will also increase participation in Innovation Center models because, unlike the fraud and abuse waivers that have been issued for certain Innovation Models, the exceptions will not expire and are not narrowly designed to apply solely to one specific model, allowing parties to enter into value-based arrangements of their own design and to continue such arrangements beyond expiration of fraud and abuse waivers. We also believe that applying the new exceptions will make compliance more straightforward for physicians and entities participating in Innovation Center models, thus resulting in cost savings for these parties. In addition, we believe that the new exceptions for arrangements intended to facilitate the transition to value-based health care delivery and payment will ensure that the physician self-referral law continues to provide meaningful protection against overutilization and other harms, thus preventing increased Medicare expenditures and associated beneficiary liability. We lack data to quantify these effects and sought public comment on these impacts.

We believe that the clarifications and regulatory revisions of key terminology (specifically, the terms ''commercially reasonable'' and ''fair market value,'' the volume or value standard, and the other business generated standard) discussed in section II.B. of this final rule will have significant, ongoing benefits to all physicians and entities affected by the physician self-referral law. These terms are used throughout the physician self-referral regulations. Commenters on the proposed rule indicated that additional guidance on these terms is necessary to reduce the complexity of structuring financial arrangements to comply with the physician self-referral law.

We anticipate that the changes to decouple the physician self-referral law regulations from the anti-kickback statute and federal and state laws or regulations governing billing or claims submission will reduce burden by making compliance more straightforward for physicians and entities. We stress that the anti-kickback statute and billing laws remain in full force and effect, so those laws will continue to protect against program and patient abuse. We anticipate that our changes to the definitions of ''designated health services,'' ''physician,'' and ''remuneration'' and the changes to the ownership and investment interest provisions in § 411.354(b) will reduce compliance burden by appropriately applying the physician self-referral law's prohibitions and providing protection for nonabusive financial relationships. Our changes for the exceptions for fair market value payments by a physician and fair market value compensation will make these exceptions available to protect financial arrangements that must currently meet more complicated and burdensome requirements of other exceptions. We anticipate that this added flexibility will provide substantial burden reduction through reduced compliance costs.

We have also finalized numerous other changes that, while relatively minor in scope, are intended to collectively reduce burden. For example, the new special rules on the set in advance requirement clarifies the requirements for modifying compensation terms during the course of an arrangement and correct a common misperception among stakeholders that parties may only modify the compensation terms of an arrangement once during the course of a year. We anticipate that our changes relating to isolated transactions, the period of disallowance, the special rules on compensation arrangements, the exceptions for rental of office space and rental of office equipment, the exception for physician recruitment, and the exception for assistance to compensate a nonphysician practitioner will also have a beneficial impact by reducing the existing burden on physicians and entities through the provision of additional guidance and clarifications. We lack data to quantify these effects and sought public comment on these impacts.

As we stated in the proposed rule, the American Hospital Association estimated compliance costs faced by hospitals.[63] It estimated $350,000[64] in annual costs for an average hospital to comply with fraud and abuse regulations, which include the physician self-referral law. To estimate aggregate fraud and abuse compliance costs, we multiply this figure by the number of Medicare enrolled hospitals, which implies $2.1 billion in total annual costs across these hospitals. Based on CMS RFI comments, compliance with the physician self-referral regulations comprises a substantial fraction of these costs. We anticipate that clarifications provided in this final rule may substantially reduce the complexity of compliance for affected entities. As a result, we expect this rule will substantially reduce net fraud and abuse compliance burden for affected entities, although we lack data to quantify these estimates. We note that hospitals represent a fraction of entities affected by this final rule, and burden is likely to decline substantially for other categories of entities affected by this rule. We sought public comment on the

[63] *https://www.aha.org/sites/default/files/regulatory-overload-report.pdf.*

[64] Note that the figure is adjusted for inflation between 2017 and 2018.

extent to which this rule will reduce compliance burden for hospitals and entities other than hospitals.

Our final modifications to the EHR exception are modest and clarify that the exception applies to certain cybersecurity technology that is included as part of an electronic health records arrangement, make the exception permanent, and clarify that contribution requirements collected from physicians for updates to previously donated technology need only be collected at reasonable intervals. The EHR exception will continue to be available to physicians and entities other than laboratories. We expect that the same entities that currently use the EHR exception will continue to use the exception. We anticipate that our final policies will result in an incremental reduction in compliance burden.

In section II.E. of this final rule, we discuss new exceptions for limited remuneration to a physician and the provision of cybersecurity technology and related services. We anticipate that the new exception for limited remuneration to a physician will ease compliance burden because it allows entities to compensate a physician for items or services provided by the physician without being subject to all the documentation and certain other requirements of existing exceptions to the physician self-referral law. We believe that this new exception will also provide additional flexibility where these arrangements are not covered by an existing exception. We anticipate that the cybersecurity exception will be widely used by physicians, group practices, and hospitals. We believe that this exception will help to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the safe and effective delivery of health care. We lack data to quantify these effects and sought public comment on these impacts.

We received the following comments and our responses follow.

Comment: The vast majority of commenters supported our proposals, noting generally that the proposed provisions will facilitate compliance with the physician self-referral law and achieve the reduced burden CMS anticipates, although no commenters provided data or other detail that would allow us to quantify the anticipated effects.

Response: We appreciate commenters' feedback confirming our assessment that this final rule will ease compliance with the physician self-referral law and reduce burden on hospitals and other entities.

Comment: A few commenters asserted that the establishment of the accountable body or person and the development of the governing document would require the expenditure of significant resources, including legal expenses, and questioned whether adding this burden was necessary.

Response: As discussed in detail in section II.A.2.a. of this final rule, we continue to believe that a value-based enterprise would ordinarily develop a governing document and that this final rule will not result in additional burden in that regard. In addition, we have provided additional guidance about these requirements, including that we are not dictating the format or content of the governing document or the structure or composition of the accountable body. Each value-based enterprise has the flexibility to develop and implement the necessary infrastructure to effectively oversee its financial and operational activities commensurate with the size and structure of the value-based enterprise.

Comment: One commenter expressed concern that the revised definition of ''remuneration'' would increase the burden on parties to monitor the use of items, devices, or services to ensure that physicians are in fact using the items, devices, or services for one or more of the permitted purposes under the statute.

Response: As we mentioned in section II.D.2.d. of this final rule, we believe that it would be impossible for an entity to monitor how a physician ''in fact'' uses a multi-use item, device, or supply whose primary purpose is not one or more of the permitted purposes to ensure that the physician in fact uses the item, device, or supply exclusively for one or more of the permitted purposes. However, we believe that the final definition of ''remuneration'' will not increase the burden of monitoring, because the provision of multi-use items, devices, or supplies whose primary purpose is not one or more of the permitted purposes will not be carved out of the definition of ''remuneration.''

Comment: Many commenters maintained that the proposed amendment to clarify the definition of ''transaction'' at § 411.351 would reduce flexibility and increase the burden of compliance.

Response: We discussed this policy in section II.D.2.e. of this final rule and explained that the revision simply clarifies an existing policy that the exception for isolated transactions is not available to protect a single payment for multiple or repeated services. This longstanding policy is based on our interpretation of the statute and our mandate under sections 1877(b)(4) and 1877(e)(6)(B) of the Act to permit only those financial relationships that do not pose a risk of program or patient abuse. We do not believe that clarifying existing policy will result in additional burden, particularly in light of new flexibilities included in this final rule.

D. Alternatives Considered

This final rule contains a range of policies. The preceding preamble presents rationale for our policies and, where relevant, alternatives that were considered. We carefully considered the alternative of maintaining the status quo and not pursuing regulatory action. However, we believe that the transition to a value-based health care delivery and payment system is urgently needed due to unsustainable costs inherent in the current volume-based system. We believe this final rule addresses the critical need for additional flexibility that is necessary to advance the transition to value-based health care and improve the coordination of care among providers in both the Federal and commercial sectors.

We also considered proposing to limit the new exceptions for arrangements that facilitate the transition to value-based health care delivery and payment to CMS-sponsored models or establishing separate exceptions with different criteria for arrangements that exist outside CMS-sponsored models. However, we believe that, in their current state, the physician self-referral regulations impede the development and adoption of innovative approaches to delivering health care, across all patient populations and payor types, and over indefinite periods of time. In addition, we considered establishing an exception to protect care coordination activities performed outside of a value-based enterprise. We rejected this alternative due to program integrity concerns that could exist without the incentives and protections inherent in a value-based enterprise and value-based arrangement, as defined at final § 411.351.

We considered including provisions in the exceptions for value-based arrangements that would require compensation to be set in advance, fair market value, and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated between the parties. We are concerned, however, that the inclusion of such requirements would conflict with our goal of dismantling and addressing

regulatory barriers to value-based care transformation. We further believe that the disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address that are built into the value-based definitions will operate in tandem with the requirements included in the exceptions and be sufficient to protect against program and patient abuse. We also considered whether to exclude laboratories and DMEPOS suppliers from the definition of ''VBE participant.'' We stated in the proposed rule that it was not clear to us that laboratories and DMEPOS suppliers have the direct patient contacts that would justify their inclusion as parties working under a protected value-based arrangement to achieve the type of patient-centered care that is a core tenet of care coordination and a value-based health care system. As discussed in Section II.A.2.a. of this final rule, we have not excluded any entities from the final definition of ''VBE participant.''

Through our own experience administering the physician self-referral regulations and our thorough analysis of comments, we recognize the urgent and compelling need for additional guidance on the physician self-referral law. In preparing this rule, we conducted an in-depth review of our existing regulations to identify those matters that might benefit from additional guidance. We took great care to provide this guidance in the clearest, most straightforward manner possible. For example, we considered addressing the need for guidance on the applicability of the physician self-referral law to referrals for inpatient hospital services after admission through modifying the definition of ''referral'' rather than the definition of ''designated health services.'' We are concerned that modifying the definition of ''referral'' could have a broader effect and would not be as clear, and declined to adopt that approach. We have also carefully weighed each proposal to ensure that it does not pose a risk of program or patient abuse. For example, we considered whether to eliminate the requirement that a physician must pay 15 percent of the cost of donated electronic health records items and service, but are concerned that doing so would pose a risk of program or patient abuse. We sought comments on these regulatory alternatives. As discussed in section II.D.11.e. of this final rule, the EHR exception maintains the 15 percent contribution requirement.

We received no comments specific to the alternatives considered section of the proposed rule.

E. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), we have prepared an accounting statement. The following table provides estimated annualized costs through 2029.

ACCOUNTING STATEMENT—ESTIMATED ANNUALIZED COSTS

Category	Primary estimate	Low estimate	High estimate	Year dollar	Discount rate (percent)	Period covered
Costs						
Annualized Monetized ($millions/year)	4.3	0.0	0.0	2018	7%	2020–2029
	3.6	0.0	0.0	2018	3	2020–2029
Annualized Quantified	0.0	0.0	0.0		7	
	0.0	0.0	0.0		3	
Qualitative						

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

DISCLAIMER: Based on the tight time constraints and the need to expedite the clearance process to ensure timely publication, OSORA will continue to work with CM to ensure that regulations text is in compliance with the Office of the Federal Register standards and guidance.

List of Subjects in 42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 411 as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

■ 2. Subpart J is amended by revising §§ 411.350 through 411.357 to read as follows:

Sec.

* * * * *

411.350 Scope of subpart.
411.351 Definitions.
411.352 Group practice.
411.353 Prohibition on certain referrals by physicians and limitations on billing.
411.354 Financial relationship, compensation, and ownership or investment interest.
411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.
411.356 Exceptions to the referral prohibition related to ownership or investment interests.
411.357 Exceptions to the referral prohibition related to compensation arrangements.

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare report information concerning

ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

(d) This subpart does not alter an individual's or entity's obligations under—

(1) The rules regarding reassignment of claims (§ 424.80 of this chapter);

(2) The rules regarding purchased diagnostic tests (§ 414.50 of this chapter);

(3) The rules regarding payment for services and supplies incident to a physician's professional services (§ 410.26 of this chapter); or

(4) Any other applicable Medicare laws, rules, or regulations.

§ 411.351 Definitions.

The definitions in this subpart apply only for purposes of section 1877 of the Act and this subpart. As used in this subpart, unless the context indicates otherwise:

Centralized building means all or part of a building, including, for purposes of this subpart only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider or supplier (for example, a diagnostic imaging facility) is not a centralized building for purposes of this subpart. This provision does not preclude a group practice from providing services to other providers or suppliers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are clinical laboratory services for purposes of this subpart. Any service not specifically identified as a clinical laboratory service on the List of CPT/HCPCS Codes is not a clinical laboratory service for purposes of this subpart.

Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

(1) The physician's opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.

(2) The request and need for the consultation are documented in the patient's medical record.

(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Cybersecurity means the process of protecting information by preventing, detecting, and responding to cyberattacks.

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

(1)(i) Clinical laboratory services.

(ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.

(iii) Radiology and certain other imaging services.

(iv) Radiation therapy services and supplies.

(v) Durable medical equipment and supplies.

(vi) Parenteral and enteral nutrients, equipment, and supplies.

(vii) Prosthetics, orthotics, and prosthetic devices and supplies.

(viii) Home health services.

(ix) Outpatient prescription drugs.

(x) Inpatient and outpatient hospital services.

(2) Except as otherwise noted in this subpart, the term ''designated health services'' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are paid by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at § 416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable under a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS):

(i) Acute Care Hospital Inpatient (IPPS);

(ii) Inpatient Rehabilitation Facility (IRF PPS);

(iii) Inpatient Psychiatric Facility (IPF PPS);

or (iv) Long-Term Care Hospital (LTCH PPS).

Does not violate the anti-kickback statute, as used in this subpart only, means that the particular arrangement—

(1)(i) Meets a safe harbor under the anti-kickback statute, as set forth at § 1001.952 of this title, ''Exceptions'';

(ii) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (for example, the entity furnishing DHS) with respect to the particular arrangement (and not a similar arrangement), provided that the arrangement is conducted in accordance with the facts certified by the requesting party and the opinion is otherwise issued in accordance with part 1008 of this title, ''Advisory Opinions by the OIG''; or

(iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(2) For purposes of this definition, a favorable advisory opinion means an opinion in which the OIG opines that—

(i) The party's specific arrangement does not implicate the anti-kickback statute, does not constitute prohibited remuneration, or fits in a safe harbor under § 1001.952 of this title; or

(ii) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128A(a)(7) and 1128(b)(7) of the Act) in connection with the party's specific arrangement.

Downstream contractor means a ''first tier contractor'' as defined at § 1001.952(t)(2)(iii) of this title or a

''downstream contractor'' as defined at § 1001.952(t)(2)(i) of this title.

Durable medical equipment (DME) and supplies has the meaning given in section 1861(n) of the Act and § 414.202 of this chapter.

Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

Employee means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Entity means—

(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—

(i) Is the person or entity that has performed services that are billed as DHS; or

(ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned in accordance with § 424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at § 1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

(2) A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier under § 424.80(b)(1) and (b)(2) of this chapter, with respect to any DHS provided by that supplier.

(3) For purposes of this subpart, ''entity'' does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with § 414.50 of this chapter and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.9.

Fair market value means—

(1) *General.* The value in an arm's-length transaction, consistent with the general market value of the subject transaction.

(2) *Rental of equipment.* With respect to the rental of equipment, the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.

(3) *Rental of office space.* With respect to the rental of office space, the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General market value means—

(1) *Assets.* With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of *bona fide* bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.

(2) *Compensation.* With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

(3) *Rental of equipment or office space.* With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of *bona fide* bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

Home health services means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter.

Hospital means any entity that qualifies as a ''hospital'' under section 1861(e) of the Act, as a ''psychiatric hospital'' under section 1861(f) of the Act, or as a ''critical access hospital'' under section 1861(mm)(1) of the Act, and refers to any separate legally organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a ''hospital'' does not include entities that perform services for hospital patients ''under arrangements'' with the hospital.

HPSA means, for purposes of this subpart, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

''*Incident to*'' *services* or *services* ''*incident to*'' means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, § 410.26 of this chapter, and Pub. 100–02, Medicare Benefit Policy Manual, Chapter 15, Sections 60, 60.1, 60.2, 60.3, and 60.4.

Inpatient hospital services means those services defined in section 1861(b) of the Act and § 409.10(a) and (b) of this chapter and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient critical access hospital services, as defined in section 1861(mm)(2) of the Act. ''Inpatient hospital services'' do not include emergency inpatient services provided by a hospital located outside of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. ''Inpatient hospital services'' also do not include dialysis furnished by a hospital that is not certified to provide end-stage renal dialysis (ESRD) services under subpart U of part 405 of this chapter. ''Inpatient hospital services'' include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. ''Inpatient hospital services'' do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists if Medicare reimburses the services independently and not as part of the

inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Interoperable means—

(1) Able to securely exchange data with and use data from other health information technology; and

(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law.

Isolated financial transaction—(1) Isolated financial transaction means a one-time transaction involving a single payment between two or more persons or a one-time transaction that involves integrally related installment payments, provided that—

(i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and

(ii) The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

(2) An isolated financial transaction includes a one-time sale of property or a practice, single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated).

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually, as published in the **Federal Register**, and is posted on the CMS website at *http://www.cms.hhs.gov/PhysicianSelfReferral/11__List__of__Codes.asp#TopOfPage*.

Locum tenens physician (or substitute physician) means a physician who substitutes in exigent circumstances for another physician, in accordance with section 1842(b)(6)(D) of the Act and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.11.

Member of the group or member of a group practice means, for purposes of this subpart, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes ''patient care services'' to the group as defined in this section. An independent contractor or a leased employee is not a member of the group (unless the leased employee meets the definition of an ''employee'' under this section).

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (s)(2)(C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient critical access hospital services, as defined in section 1861(mm)(3) of the Act. ''Outpatient hospital services'' do not include emergency services furnished by nonparticipating hospitals and covered under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. ''Outpatient hospital services'' include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. ''Outpatient hospital services'' do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Outpatient prescription drugs means all drugs covered by Medicare Part B or D, except for those drugs that are ''covered ancillary services,'' as defined at § 416.164(b) of this chapter, for which separate payment is made to an ambulatory surgical center.

Parenteral and enteral nutrients, equipment, and supplies means the following services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies,* meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies,* meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2.

Patient care services means any task(s) performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

Physical therapy, occupational therapy, and outpatient speech-language pathology services means those particular services so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this subpart. Any service not specifically identified as physical therapy, occupational therapy or outpatient speech-language pathology on the List of CPT/HCPCS Codes is not a physical therapy, occupational

therapy, or outpatient speech-language pathology service for purposes of this subpart. The list of codes identifying physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this regulation includes the following:

(1) *Physical therapy services,* meaning those outpatient physical therapy services described in section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests, and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment; or

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been reached; however, maintenance therapy itself is not covered as part of these services.

(2) *Occupational therapy services,* meaning those services described in section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;

(ii) Evaluation of an individual's level of independent functioning;

(iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or

(iv) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(3) *Outpatient speech-language pathology services,* meaning those services as described in section 1861(ll)(2) of the Act that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

Physician has the meaning set forth in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in § 424.80(b)(2) of this chapter (*see* also Pub. L. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

Physician incentive plan means any compensation arrangement between an entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Physician organization means a physician, a physician practice, or a group practice that complies with the requirements of § 411.352.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of services.

Professional courtesy means the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these items and services that are covered by Medicare):

(1) *Orthotics,* meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) *Prosthetics,* meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) *Prosthetic devices,* meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(4) *Prosthetic supplies,* meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies, including (effective January 1, 2007) therapeutic nuclear medicine services and supplies, so identified on the List of CPT/HCPCS Codes. All services and supplies so identified on the List of CPT/HCPCS Codes are radiation therapy services and supplies for purposes of this subpart. Any service or supply not specifically identified as radiation therapy services or supplies on the List of CPT/HCPCS Codes is not a radiation therapy service or supply for purposes of this subpart. The list of codes identifying radiation therapy services and supplies is based on section 1861(s)(4) of the Act and § 410.35 of this chapter.

Radiology and certain other imaging services means those particular services so identified on the List of CPT/HCPCS Codes. All services identified on the List of CPT/HCPCS Codes are radiology and certain other imaging services for purposes of this subpart. Any service not specifically identified as radiology and certain other imaging services on the List of CPT/HCPCS Codes is not a radiology or certain other imaging service for purposes of this subpart. The list of codes identifying radiology and certain other imaging services includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, computerized axial tomography, magnetic resonance imaging, nuclear medicine (effective January 1, 2007), or other imaging services. All codes identified as radiology and certain other imaging services are covered under section 1861(s)(3) of the Act and §§ 410.32 and 410.34 of this chapter, but do not include—

(1) X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(2) Radiology or certain other imaging services that are integral to the performance of a medical procedure that is not identified on the list of CPT/HCPCS codes as a radiology or certain other imaging service and is performed—

(i) Immediately prior to or during the medical procedure; or

(ii) Immediately following the medical procedure when necessary to confirm placement of an item placed during the medical procedure.

(3) Radiology and certain other imaging services that are ''covered ancillary services,'' as defined at § 416.164(b), for which separate payment is made to an ASC.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if—

(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

(4) A referral is not an item or service for purposes of section 1877 of the Act and this subpart.

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity. A referring physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies that are, in fact, used solely for one or more of the following purposes:

(i) Collecting specimens for the entity furnishing the items, devices or supplies;

(ii) Transporting specimens for the entity furnishing the items, devices or supplies;

(iii) Processing specimens for the entity furnishing the items, devices or supplies;

(iv) Storing specimens for the entity furnishing the items, devices or supplies;

(v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or

(vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies.

(3) A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in any manner that takes into account the volume or value of referrals.

Rural area means an area that is not an urban area as defined at § 412.62(f)(1)(ii) of this chapter.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior loading docks or parking garages. For purposes of this section, the ''same building'' does not include a mobile vehicle, van, or trailer.

Specialty hospital means:

(1) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act) that is primarily or exclusively engaged in the care and treatment of one of the following:

(i) Patients with a cardiac condition;

(ii) Patients with an orthopedic condition;

(iii) Patients receiving a surgical procedure; or

(iv) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital.

(2) A ''specialty hospital'' does not include any hospital—

(i) Determined by the Secretary to be in operation before or under development as of November 18, 2003;

(ii) For which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(iii) For which the type of categories described above is no different at any time on or after such date than the type of such categories as of such date;

(iv) For which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(v) That meets such other requirements as the Secretary may specify.

Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and

(2) Further the value-based enterprise's value-based purpose(s).

Transaction means an instance of two or more persons or entities doing business.

Value-based activity means any of the following activities, provided that the

activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(1) The provision of an item or service;

(2) The taking of an action; or

(3) The refraining from taking an action.

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are—

(1) The value-based enterprise and one or more of its VBE participants; or

(2) VBE participants in the same value-based enterprise.

Value-based enterprise (VBE) means two or more VBE participants—

(1) Collaborating to achieve at least one value-based purpose;

(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-based purpose means any of the following:

(1) Coordinating and managing the care of a target patient population;

(2) Improving the quality of care for a target patient population;

(3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or

(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

VBE participant means a person or entity that engages in at least one value-based activity as part of a value-based enterprise.

§ 411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity.* The group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this subpart, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a single legal entity may itself own subsidiary entities. A group practice operating in more than one State will be considered to be a single legal entity notwithstanding that it is composed of multiple legal entities, provided that—

(1) The States in which the group practice is operating are contiguous (although each State need not be contiguous to every other State);

(2) The legal entities are absolutely identical as to ownership, governance, and operation; and

(3) Organization of the group practice into multiple entities is necessary to comply with jurisdictional licensing laws of the States in which the group practice operates.

(b) *Physicians.* The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined at § 411.351.

(c) *Range of care.* Each physician who is a member of the group, as defined at § 411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) *Services furnished by group practice members.* (1) Except as otherwise provided in paragraphs (d)(3) through (6) of this section, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. *Patient care services* must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30 hours a week on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this *substantially all* test and related supportive documentation must be made available to the Secretary upon request.

(3) The *substantially all* test set forth in paragraph (d)(1) of this section does not apply to any group practice that is located solely in a HPSA, as defined at § 411.351.

(4) For a group practice located outside of a HPSA (as defined at § 411.351), any time spent by a group practice member providing services in a HPSA should not be used to calculate whether the group practice has met the *substantially all* test, regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the *start up* period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the *substantially all* test requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or reorganizes.

(6)(i) If the addition to an existing group practice of a new member who would be considered to have relocated his or her medical practice under § 411.357(e)(2) would result in the existing group practice not meeting the *substantially all* test set forth in paragraph (d)(1) of this section, the group practice will have 12 months following the addition of the new member to come back into full compliance, provided that—

(A) For the 12-month period the group practice is fully compliant with the *substantially all* test if the new member

is not counted as a member of the group for purposes of § 411.352; and

(B) The new member's employment with, or ownership interest in, the group practice is documented in writing no later than the beginning of his or her new employment, ownership, or investment.

(ii) This paragraph (d)(6) does not apply when an existing group practice reorganizes or admits a new member who is not relocating his or her medical practice.

(e) *Distribution of expenses and income.* The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this section prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under paragraph (i) of this section.

(f) *Unified business.* (1) The group practice must be a unified business having at least the following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and

(ii) Consolidated billing, accounting, and financial reporting.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under paragraph (i) of this section.

(g) *Volume or value of referrals.* No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in paragraph (i) of this section.

(h) *Physician-patient encounters.* Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) *Special rule for productivity bonuses and profit shares.* (1) A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed, or services ''incident to'' such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services ''incident to'' the physician's personally performed services).

(2) Overall profits means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. Overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(i) The group's profits are divided per capita (for example, per member of the group or per physician in the group).

(ii) Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group.

(3) A productivity bonus must be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS if one of the following conditions is met:

(i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). (The methodology for establishing RVUs is set forth in § 414.22 of this chapter.)

(ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice.

(4) Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(2) and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff. However, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment for services furnished under a prohibited referral.* (1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

(2) When payment for a designated health service is denied on the basis that the service was furnished pursuant to a prohibited referral, and such payment denial is appealed—

(i) The ultimate burden of proof (burden of persuasion) at each level of appeal is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral); and

(ii) The burden of production on each issue at each level of appeal is initially on the claimant, but may shift to CMS or its contractors during the course of the appellate proceeding, depending on the evidence presented by the claimant.

(d) *Refunds.* An entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all

collected amounts on a timely basis, as defined at § 1003.101 of this title.

(e) *Exception for certain entities.* Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal and State laws, rules, and regulations.

(f) *Exception for certain arrangements involving temporary noncompliance.* (1) Except as provided in paragraphs (f)(2) through (4) of this section, an entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under § 411.355, 411.356, or 411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception; and

(ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance.

(2) Paragraph (f)(1) of this section applies only to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception.

(3) Paragraph (f)(1) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) Paragraph (f)(1) does not apply if the exception with which the financial relationship previously complied was § 411.357(k) or (m).

(g) [Reserved]

(h) *Special rule for reconciling compensation.* An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(1) No later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) that are parties to the compensation arrangement reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and

(2) Except for the discrepancies in payments described in paragraph (h)(1) of this section, the compensation arrangement fully complies with an applicable exception in this subpart.

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships*—(1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) *Types of financial relationships.* (i) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).

(ii) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest in the entity may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, stock options other than those described in paragraph (b)(3)(ii) of this section, partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in an entity that arises from a retirement plan offered by that entity to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity;

(ii) Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to equity (before this time the stock options or convertible securities are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section);

(iv) An ''under arrangements'' contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS ''under arrangements'' with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section);

(v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a compensation arrangement as defined in paragraph (c) of this section);

(vi) A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under Internal Revenue Code section 401(a).

(4) An ownership or investment interest that meets an exception set forth in § 411.355 or § 411.356 need not also meet an exception for compensation arrangements set forth in § 411.357 with respect to profit distributions, dividends, or interest payments on secured obligations.

(5)(i) An *indirect ownership or investment interest* exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) An indirect ownership or investment interest exists even though the entity furnishing DHS does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(iii) Notwithstanding anything in this paragraph (b)(5), common ownership or investment in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor.

(iv) An indirect ownership or investment interest requires an unbroken chain of ownership interests between the referring physician and the entity furnishing DHS such that the referring physician has an indirect ownership or investment interest *in* the entity furnishing DHS.

(c) *Compensation arrangement.* A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An ''under arrangements'' contract between a hospital and an entity providing DHS ''under arrangements'' to the hospital creates a compensation arrangement for purposes of these regulations. A compensation arrangement does not include the portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term ''remuneration'' at § 411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(1)(i) A direct compensation arrangement exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities.

(ii) Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to ''stand in the shoes'' of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if—

(A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and

(B) The physician has an ownership or investment interest in the physician organization.

(iii) A physician (other than a physician described in paragraph (c)(1)(ii)(B) of this section) is permitted to ''stand in the shoes'' of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization.

(2) An *indirect compensation arrangement* exists if all of the conditions of paragraphs (c)(2)(i) through (iii) of this section exist:

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link).

(ii)(A) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and the individual unit of compensation received by the physician (or immediate family member)—

(*1*) Is not fair market value for items or services actually provided;

(*2*) Includes the physician's referrals to the entity furnishing DHS as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or

(*3*) Includes other business generated by the physician for the entity furnishing DHS as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity.

(B) For purposes of applying paragraph (c)(2)(ii)(A) of this section, a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(C) If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)).

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(iv)(A) For purposes of paragraph (c)(2)(i) of this section, except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to ''stand in the shoes'' of his or her physician organization if the physician has an ownership or investment interest in the physician organization.

(B) For purposes of paragraph (c)(2)(i) of this section, a physician (other than a physician described in paragraph (c)(2)(iv)(A) of this section) is permitted to ''stand in the shoes'' of his or her physician organization.

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv) of this section, a physician who ''stands in the shoes'' of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. When applying the exceptions in §§ 411.355 and 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the ''parties to the arrangements'' are considered to be—

(A) With respect to a signature requirement, the physician organization and any physician who ''stands in the shoes'' of the physician organization as required under paragraph (c)(1)(ii) or (c)(2)(iv)(A) of this section; and

(B) With respect to all other requirements of the exception, including the relevant referrals and other business generated between the parties, the entity furnishing DHS and the physician organization (including

all members, employees, and independent contractor physicians).

(ii) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv)(A) of this section—

(A) Need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of § 411.357(p) as of September 5, 2007 (see 42 CFR parts 400–413, revised as of October 1, 2007);

(B) Do not apply to an arrangement that satisfies the requirements of § 411.355(e); and

(C) Do not apply to a physician whose ownership or investment interest is titular only. A titular ownership or investment interest is an ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.

(iii) An arrangement structured to comply with an exception in § 411.357 (other than § 411.357(p)), but which would otherwise qualify as an indirect compensation arrangement under this paragraph as of August 19, 2008, need not be restructured to satisfy the requirements of § 411.357(p) until the expiration of the original term or current renewal term of the arrangement.

(4)(i) *Exceptions applicable to indirect compensation arrangements—General.* Except as provided in this paragraph (c)(4) of this section, only the exceptions at §§ 411.355 and 411.357(p) are applicable to indirect compensation arrangements.

(ii) *Special rule for indirect compensation arrangements involving a MCO or IPA and a referring physician.* Only the exceptions at §§ 411.355, 411.357(n), and 411.357(p) are applicable in the case of an indirect compensation arrangement in which the entity furnishing DHS described in paragraph (c)(2)(i) of this section is a MCO or IPA.

(iii) *Special rule for indirect compensation arrangements involving value-based arrangements.* When an unbroken chain described in paragraph (c)(2)(i) of this section includes a value-based arrangement (as defined at § 411.351) to which the physician (or the physician organization in whose shoes the physician stands under this paragraph) is a direct party—

(A) Only the exceptions at §§ 411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is not a MCO or IPA; and

(B) Only the exceptions at §§ 411.355, 411.357(n), 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is a MCO or IPA.

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and subpart J of this part:

(1) *Set in advance.* (i) Compensation is deemed to be ''set in advance'' if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items, services, office space, or equipment for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified.

(ii) Notwithstanding paragraph (d)(1)(i) of this section, compensation (or a formula for determining the compensation) may be modified at any time during the course of a compensation arrangement and satisfy the requirement that it is ''set in advance'' if all of the following conditions are met:

(A) All requirements of an applicable exception in §§ 411.355 through 411.357 are met on the effective date of the modified compensation (or the formula for determining the modified compensation).

(B) The modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid.

(C) Before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified. Paragraph (e)(4) of this section does not apply for purposes of this paragraph (d)(1)(ii)(C).

(2) *Unit-based compensation and the volume or value standard.* Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account the volume or value of referrals if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of designated health services. This paragraph (d)(2) does not apply for purposes of paragraphs (d)(5)(i) and (6)(i) of this section.

(3) *Unit-based compensation and the other business generated standard.* Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account other business generated between the parties or other business generated by the referring physician if the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which are not considered ''other business generated'' by the referring physician). This paragraph (d)(3) does not apply for purposes of paragraphs (d)(5)(ii) and (d)(6)(ii) of this section.

(4) *Directed referral requirement.* If a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, all of the following conditions must be met.

(i) The compensation, or a formula for determining the compensation, is set in advance for the duration of the arrangement. Any changes to the compensation (or the formula for determining the compensation) must be made prospectively.

(ii) The compensation is consistent with the fair market value of the physician's services.

(iii) The compensation arrangement otherwise satisfies the requirements of an applicable exception at § 411.355 or § 411.357.

(iv) The compensation arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, personal service arrangement, or managed care contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make

referrals that relate to services that are not provided by the physician under the scope of his or her employment, personal service arrangement, or managed care contract.

(vi) Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as set forth at paragraph (d)(5)(i) of this section, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

(5) *Compensation to a physician.* (i) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity.

(ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if the formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity.

(iii) For purposes of applying this paragraph (d)(5), a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(iv) This paragraph (d)(5) does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this section or the exceptions at § 411.357(m), (s), (u), (v), (w), and (bb).

(6) *Compensation from a physician.* (i) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if the formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity.

(ii) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of other business generated only if the formula used to calculate the entity's compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the physician's generation of other business for the entity.

(iii) For purposes of applying this paragraph (d)(6), a negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.

(iv) This paragraph (d)(6) does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this section or the exceptions at § 411.357(m), (s), (u), (v), (w), and (bb).

(e) *Special rule on compensation arrangements*—(1) *Application.* This paragraph (e) applies only to compensation arrangements as defined in section 1877 of the Act and this subpart.

(2) *Writing requirement.* In the case of any requirement in this subpart for a compensation arrangement to be in writing, such requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

(3) *Signature requirement.* In the case of any signature requirement in this subpart, such requirement may be satisfied by an electronic or other signature that is valid under applicable Federal or State law.

(4) *Special rule on writing and signature requirements.* In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if—

(i) The compensation arrangement between the entity and the physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and

(ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception (that is, the date on which the writing(s) or signature(s) were required under the applicable exception but the parties had not yet obtained them).

§ 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined at § 410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at § 411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at § 411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of this paragraph (a), ''physician services'' include only those ''incident to'' services (as defined at § 411.351) that are physician services under § 410.20(a) of this chapter.

(b) *In-office ancillary services.* Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN)), that meet the following conditions:

(1) *Individual who furnishes the service.* They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) An individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.

(2) *Location where service is furnished.* They are furnished in one of the following locations:

(i) The same building (as defined at § 411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), *or* (b)(2)(i)(C) of this section are satisfied:

(A)(*1*) The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; and

(*2*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(B)(*1*) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(*3*) The referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(C)(*1*) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section *or* the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section;

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(*3*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

(ii) A centralized building (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) *Billing of the service.* They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a ''physician in the group practice'' (as defined at § 411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (iv) of this section under a billing number assigned to the physician, group practice, or entity, provided that the billing arrangement meets the requirements of § 424.80(b)(5) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) *Durable Medical Equipment.* For purposes of this paragraph (b), DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purpose of ambulating, a patient uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the ''same building'' requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards set forth in § 424.57(c) of this chapter.

(v) [Reserved]

(vi) All other requirements of the in-office ancillary services exception in this paragraph (b) are met.

(5) *Furnishing a service.* A designated health service is ''furnished'' for purposes of this paragraph (b) in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the ''same building'' requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section only, a private home does not include a nursing, long-term care, or other facility or institution, except that a patient may have a private home in an assisted living or independent living facility.

(7) *Disclosure requirement for certain imaging services.* (i) With respect to magnetic resonance imaging, computed tomography, and positron emission tomography services identified as ''radiology and certain other imaging services'' on the List of CPT/HCPCS Codes, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in paragraph (b)(1) of this section. Except as set forth in paragraph (b)(7)(ii) of this section, the written notice must include a list of at least 5 other suppliers (as defined at § 400.202 of this chapter) that

provide the services for which the individual is being referred and which are located within a 25-mile radius of the referring physician's office location at the time of the referral. The notice should be written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier's name, address, and telephone number.

(ii) If there are fewer than 5 other suppliers located within a 25-mile radius of the physician's office location at the time of the referral, the physician must list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician's office location. Provision of the written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M of this chapter.

(2) A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(6) A MCO contracting with a State under section 1903(m) of the Act.

(7) A prepaid inpatient health plan (PIHP) or prepaid ambulance health plan (PAHP) contracting with a State under part 438 of this chapter.

(8) A health insuring organization (HIO) contracting with a State under part 438, subpart D of this chapter.

(9) An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

(d) [Reserved]

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. (A ''component'' of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;

(B) Is licensed to practice medicine in the State(s) in which he or she practices medicine;

(C) Has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital (as defined at § 411.355(e)(3)); and

(D) Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph (e)(1)(i)(D).

(ii) The compensation paid to the referring physician must meet all of the following conditions:

(A) The total compensation paid by each academic medical center component to the referring physician is set in advance.

(B) In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.

(C) The total compensation paid by each academic medical center component is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician within the academic medical center.

(D) If any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant.

(2) The ''academic medical center'' for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital (as defined at paragraph (e)(3) of this section);

(ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and

(iii) One or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members. The hospital for purposes of this paragraph (e)(2)(iii) may be the same hospital that satisfies the requirement of paragraph (e)(2)(i) of this section. For purposes of this paragraph (e)(2)(iii), a faculty member is a physician who is

either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. In meeting this paragraph (e)(2)(iii), faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals need not be counted. Any faculty member may be counted, including courtesy and volunteer faculty. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

(3) An accredited academic hospital for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs.

(f) *Implants furnished by an ASC.* Implants furnished by an ASC, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices, and implanted DME that meet the following conditions:

(1) The implant is implanted by the referring physician or a member of the referring physician's group practice in an ASC that is certified by Medicare under part 416 of this chapter and with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure under § 416.65 of this chapter.

(3) [Reserved]

(4) [Reserved]

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to, and implanted in, the patient.

(g) *EPO and other dialysis-related drugs.* EPO and other dialysis-related drugs that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph (g)(1), ''EPO and other dialysis-related drugs'' means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and ''furnished'' means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.

(2) [Reserved]

(3) [Reserved]

(4) The exception set forth in this paragraph (g) does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests, immunizations, and vaccines.* Preventive screening tests, immunizations, and vaccines that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated frequency limits.

(2) [Reserved]

(3) [Reserved]

(4) The preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed as eligible for this exception on the List of CPT/HCPCS Codes.

(i) *Eyeglasses and contact lenses following cataract surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in §§ 410.36(a)(2)(ii) and 414.228 of this chapter, respectively.

(2) [Reserved]

(j) *Intra-family rural referrals.* (1) Services provided pursuant to a referral from a referring physician to his or her immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if all of the following conditions are met:

(i) The patient who is referred resides in a rural area as defined at § 411.351 of this subpart;

(ii) Except as provided in paragraph (j)(1)(iii) of this section, in light of the patient's condition, no other person or entity is available to furnish the services in a timely manner within 25 miles of or 45 minutes transportation time from the patient's residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or DME), no other person or entity is available to furnish the services in a timely manner in light of the patient's condition; and

(2) The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles of or 45 minutes transportation time from (whichever test the referring physician utilized for purposes of paragraph (j)(1)(ii)) the patient's residence.

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis;

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; or

(iii) Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

(2) They are in a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. ''Stockholder equity'' is the difference in value between a corporation's total assets and total liabilities.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities, for purposes of the services specified:

(1) A rural provider, in the case of DHS furnished in a rural area (as defined at § 411.351 of this part) by the provider. A ''rural provider'' is an entity

that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area and, for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), is not a specialty hospital, and in the case where the entity is a hospital, the hospital meets the requirements of § 411.362 no later than September 23, 2011.

(2) A hospital that is located in Puerto Rico, in the case of DHS furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if—

(i) The referring physician is authorized to perform services at the hospital;

(ii) Effective for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), the hospital is not a specialty hospital;

(iii) The ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital; and

(iv) The hospital meets the requirements described in § 411.362 not later than September 23, 2011.

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if the arrangement meets the following requirements:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same space during the first year of the original lease arrangement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. For purposes of this paragraph (a), exclusive use means that the lessee (and any other lessees of the same office space) uses the office space to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space.

(4) The rental charges over the term of the lease arrangement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the lease arrangement are not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(6) The lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (a) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (a)(1) through (6) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (a)(1) through (6) of this section.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor). For purposes of this paragraph (b), exclusive use means that the lessee (and any other lessees of the same equipment) uses the equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the equipment.

(3) The duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same equipment during the first year of the original lease arrangement.

(4) The rental charges over the term of the lease arrangement are set in advance, are consistent with fair market value, and are not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(5) The lease arrangement would be commercially reasonable even if no referrals were made between the parties.

(6) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of this paragraph (b) if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (b)(1) through (5) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding lease arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (b)(1) through (5) of this section.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a *bona fide* employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in any manner that takes into account the volume or value of referrals by the referring physician.

(3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(d) *Personal service arrangements*—(1) *General.* Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) Except for services provided under an arrangement that satisfies all of the conditions of paragraph (z) of this section, the arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member may ''furnish'' services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice).

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The duration of each arrangement is at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at § 411.351), is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

(vii) If the arrangement expires after a term of at least 1 year, a holdover arrangement immediately following the expiration of the arrangement satisfies the requirements of paragraph (d) of this section if the following conditions are met:

(A) The arrangement met the conditions of paragraphs (d)(1)(i) through (vi) of this section when the arrangement expired;

(B) The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(C) The holdover arrangement continues to satisfy the conditions of paragraphs (d)(1)(i) through (vi) of this section.

(viii) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined at § 411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in any manner (through a withhold, capitation, bonus, or otherwise) that takes into account the volume or value of referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.

(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream contractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined at § 422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in §§ 422.208 and 422.210 of this chapter.

(iv) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(e) *Physician recruitment.* (1) Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by both parties;

(ii) The arrangement is not conditioned on the physician's referral of patients to the hospital;

(iii) The amount of remuneration under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services arrangement that complies with § 411.354(d)(4)).

(2)(i) *Geographic area served by the hospital—defined.* The ''geographic area served by the hospital'' is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. The geographic area served by the hospital may include one or more zip codes from which the hospital draws no inpatients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the hospital draws at least 75 percent of its inpatients.

(ii) *Noncontiguous zip codes.* With respect to a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the ''geographic area served by the hospital'' will be deemed to be the area composed of all of the

contiguous zip codes from which the hospital draws its inpatients.

(iii) *Special optional rule for rural hospitals.* In the case of a hospital located in a rural area (as defined at § 411.351), the ''geographic area served by the hospital'' may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the ''geographic area served by the hospital'' may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital's inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients.

(iv) *Relocation of medical practice.* A physician will be considered to have relocated his or her medical practice if the medical practice was located outside the geographic area served by the hospital and—

(A) The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; or

(B) The physician moves his medical practice into the geographic area served by the hospital, and the physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year). For the initial ''start up'' year of the recruited physician's practice, the 75 percent test in the preceding sentence will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

(3) The recruited physician will not be subject to the relocation requirement of this paragraph (e), provided that he or she establishes his or her medical practice in the geographic area served by the recruiting hospital, if—

(i) He or she is a resident or physician who has been in practice 1 year or less;

(ii) He or she was employed on a full-time basis for at least 2 years immediately prior to the recruitment arrangement by one of the following (and did not maintain a private practice in addition to such full-time employment):

(A) A Federal or State bureau of prisons (or similar entity operating one or more correctional facilities) to serve a prison population;

(B) The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or

(C) A facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service; or

(iii) The Secretary has deemed in an advisory opinion issued under section 1877(g) of the Act that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

(i) The writing in paragraph (e)(1) of this section is also signed by the physician practice if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

(ii) Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.

(iii) In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either—

(A) The actual additional incremental costs attributable to the recruited physician; or

(B) The lower of a *per capita* allocation or 20 percent of the practice's aggregate costs.

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least 6 years and made available to the Secretary upon request.

(v) The remuneration from the hospital under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

(vi) The physician practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.

(5) Recruitment of a physician by a hospital located in a rural area (as defined at § 411.351) to an area outside the geographic area served by the hospital is permitted under this exception if the Secretary determines in an advisory opinion issued under section 1877(g) of the Act that the area has a demonstrated need for the recruited physician and all other requirements of this paragraph (e) are met.

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(ii) The ''geographic area served'' by a federally qualified health center or a rural health clinic is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes from which the federally qualified health center or rural health clinic draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, or a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, if all of the following conditions are met:

(1) The amount of remuneration under the isolated financial transaction is—

(i) Consistent with the fair market value of the isolated financial transaction; and

(ii) Not determined in any manner that takes into account the volume or value of referrals by the referring physician or other business generated between the parties.

(2) The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity.

(3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in §§ 411.355 through 411.357 and except for commercially reasonable post-closing adjustments that do not take into account the volume or value of referrals or other business generated by the referring physician.

(4) An isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute.

(g) *Certain arrangements with hospitals.* Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as ''unrelated,'' remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. Remuneration relates to the furnishing of DHS if it—

(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;

(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or

(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services furnished to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before, and has continued in effect without interruption since, December 19, 1989.

(3) With respect to the DHS covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(7) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(i) *Payments by a physician.* Payments made by a physician (or his or her immediate family member)—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services—

(i) That are furnished at a price that is consistent with fair market value; and

(ii) To which the exceptions in paragraphs (a) through (h) of this section are not applicable.

(3) For purposes of this paragraph (i), ''services'' means services of any kind (not merely those defined as ''services'' for purposes of the Medicare program in § 400.202 of this chapter).

(j) *Charitable donations by a physician. Bona fide* charitable donations made by a physician (or immediate family member) to an entity if all of the following conditions are satisfied:

(1) The charitable donation is made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization);

(2) The donation is neither solicited, nor offered, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity; and

(k) *Nonmonetary compensation.* (1) Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of $300 per calendar year, as adjusted for inflation in accordance with paragraph (k)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(ii) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral website at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp*.

(3) Where an entity has inadvertently provided nonmonetary compensation to a physician in excess of the limit (as set forth in paragraph (k)(1) of this section), such compensation is deemed to be within the limit if—

(i) The value of the excess nonmonetary compensation is no more than 50 percent of the limit; and

(ii) The physician returns to the entity the excess nonmonetary compensation (or an amount equal to the value of the excess nonmonetary compensation) by the end of the calendar year in which the excess nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.

(iii) This paragraph (k)(3) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) In addition to nonmonetary compensation up to the limit described in paragraph (k)(1) of this section, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit in paragraph (k)(1).

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services or for the lease of office space or equipment by the physician (or an immediate family

member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items, services, office space, or equipment. The writing specifies—

(i) The items, services, office space, or equipment covered under the arrangement;

(ii) The compensation that will be provided under the arrangement; and

(iii) The timeframe for the arrangement.

(2) An arrangement may be for any period of time and contain a termination clause. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change. Other than an arrangement that satisfies all of the conditions of paragraph (z) of this section, the parties may not enter into more than one arrangement for the same items, services, office space, or equipment during the course of a year.

(3) The compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of office space or equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(4) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act).

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

(7) The arrangement satisfies the requirements of § 411.354(d)(4) in the case of—

(i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or

(ii) Remuneration paid to the group of physicians that is conditioned on one or more of the group's physicians' referrals to a particular provider, practitioner, or supplier.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital website or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital website or in hospital advertising, meets the ''on campus'' requirement of this paragraph (m).

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value). The $25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–I for the 12 month period and the new limits on the physician self-referral website at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.*

(6) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) [Reserved]

(8) Other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have *bona fide* medical staffs may provide compensation under this paragraph (m) on the same terms and conditions applied to hospitals under this paragraph (m).

(n) *Risk-sharing arrangements.* Compensation paid directly or indirectly by a MCO or an IPA to a physician pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) for services provided by the physician to enrollees of a health plan. For purposes of this paragraph (n), ''health plan'' and ''enrollees'' have the meanings set forth in § 1001.952(l) of this title.

(o) *Compliance training.* Compliance training provided by an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area, provided that the training is held in the local community or service area. For purposes of this paragraph (o), ''compliance training'' means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, or reporting); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided. For purposes of this paragraph, ''compliance training'' includes programs that offer continuing medical education credit, provided that compliance training is the primary purpose of the program.

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined at § 411.354(c)(2), if all of the following conditions are satisfied:

(1)(i) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated

by the referring physician for the entity furnishing DHS.

(ii) Compensation for the rental of office space or equipment may not be determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) [Reserved]

(4) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the compensation arrangement described in § 411.354(c)(2)(ii) satisfies the conditions of § 411.354(d)(4).

(q) *Referral services.* Remuneration that meets all of the conditions set forth in § 1001.952(f) of this title.

(r) *Obstetrical malpractice insurance subsidies.* Remuneration that meets all of the conditions of paragraph (r)(1) or (2) of this section.

(1) Remuneration that meets all of the conditions set forth in § 1001.952(o) of this title.

(2) A payment from a hospital, federally qualified health center, or rural health clinic that is used to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice, if all of the following conditions are met:

(i)(A) The physician's medical practice is located in a rural area, a primary care HPSA, or an area with demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's obstetrical patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The arrangement is set out in writing, is signed by the physician and the hospital, federally qualified health center, or rural health clinic providing the payment, and specifies the payment to be made by the hospital, federally qualified health center, or rural health clinic and the terms under which the payment is to be provided.

(iii) The arrangement is not conditioned on the physician's referral of patients to the hospital, federally qualified health center, or rural health clinic providing the payment.

(iv) The hospital, federally qualified health center, or rural health clinic does not determine the amount of the payment in any manner that takes into account the volume or value of referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), or rural health clinic(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services arrangement that complies with § 411.354(d)(4)).

(vi) The payment is made to a person or organization (other than the physician) that is providing malpractice insurance (including a self-funded organization).

(vii) The physician treats obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(viii) The insurance is a *bona fide* malpractice insurance policy or program, and the premium, if any, is calculated based on a *bona fide* assessment of the liability risk covered under the insurance.

(ix)(A) For each coverage period (not to exceed 1 year), at least 75 percent of the physician's obstetrical patients treated under the coverage of the obstetrical malpractice insurance during the prior period (not to exceed 1 year)—

(*1*) Resided in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(*2*) Were part of a medically underserved population.

(B) For the initial coverage period (not to exceed 1 year), the requirements of paragraph (r)(2)(ix)(A) of this section will be satisfied if the physician certifies that he or she has a reasonable expectation that at least 75 percent of the physician's obstetrical patients treated under the coverage of the malpractice insurance will—

(*1*) Reside in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(*2*) Be part of a medically underserved population.

(3) For purposes of paragraph (r)(2) of this section, *costs of malpractice insurance premiums* means:

(i) For physicians who engage in obstetrical practice on a full-time basis, any costs attributable to malpractice insurance; or

(ii) For physicians who engage in obstetrical practice on a part-time or sporadic basis, the costs attributable exclusively to the obstetrical portion of the physician's malpractice insurance, and related exclusively to obstetrical services provided—

(A) In a rural area, primary care HPSA, or an area with demonstrated need for the physician's obstetrical services, as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) In any area, provided that at least 75 percent of the physician's obstetrical patients treated in the coverage period (not to exceed 1 year) resided in a medically underserved area or were part of a medically underserved population.

(s) *Professional courtesy.* Professional courtesy (as defined at § 411.351) offered by an entity with a formal medical staff to a physician or a physician's immediate family member or office staff if all of the following conditions are met:

(1) The professional courtesy is offered to all physicians on the entity's bona fide medical staff or in such entity's local community or service area, and the offer does not take into account the volume or value of referrals or other business generated between the parties;

(2) The health care items and services provided are of a type routinely provided by the entity;

(3) The entity has a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body;

(4) The professional courtesy is not offered to a physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need; and

(t) *Retention payments in underserved areas*—(1) *Bona fide written offer.* Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area

served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician has a *bona fide* firm, written recruitment offer or offer of employment from a hospital, academic medical center (as defined at § 411.355(e)), or physician organization (as defined at § 411.351) that is not related to the hospital making the payment, and the offer specifies the remuneration being offered and requires the physician to move the location of his or her medical practice at least 25 miles *and* outside of the geographic area served by the hospital making the retention payment.

(ii) The requirements of paragraphs (e)(1)(i) through (iv) of this section are satisfied.

(iii) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the written recruitment offer or offer of employment.

(iv) The retention payment does not exceed the lower of—

(A) The amount obtained by subtracting the physician's current income from physician and related services from the income the physician would receive from comparable physician and related services in the written recruitment or employment offer, provided that the respective incomes are determined using a reasonable and consistent methodology, and that they are calculated uniformly over no more than a 24-month period; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) of this setion are satisfied.

(2) *Written certification from physician.* Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician furnishes to the hospital before the retention payment is made a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center (as defined at § 411.355(e)), or physician organization (as defined at § 411.351) that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The certification contains at least the following—

(A) Details regarding the steps taken by the physician to effectuate the employment opportunity;

(B) Details of the physician's employment opportunity, including the identity and location of the physician's future employer or employment location or both, and the anticipated income and benefits (or a range for income and benefits);

(C) A statement that the future employer is not related to the hospital making the payment;

(D) The date on which the physician anticipates relocating his or her medical practice outside of the geographic area served by the hospital; and

(E) Information sufficient for the hospital to verify the information included in the written certification.

(ii) The hospital takes reasonable steps to verify that the physician has a *bona fide* opportunity for future employment that requires the physician to relocate outside the geographic area served by the hospital.

(iii) The requirements of paragraphs (e)(1)(i) through (iv) of this section are satisfied.

(iv) The retention payment does not exceed the lower of—

(A) An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months), using a reasonable and consistent methodology that is calculated uniformly; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) of this section are satisfied.

(3) *Additional requirements.* Remuneration provided under paragraph (t)(1) or (2) of this section must meet the following additional requirements:

(i)(A) The physician's current medical practice is located in a rural area or HPSA (regardless of the physician's specialty) or is located in an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The hospital does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years.

(iii) The amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(4) *Waiver of relocation requirement.* The Secretary may waive the relocation requirement of paragraphs (t)(1) and (t)(2) of this section for payments made to physicians practicing in a HPSA or an area with demonstrated need for the physician through an advisory opinion issued in accordance with section 1877(g)(6) of the Act, if the retention payment arrangement otherwise complies with all of the conditions of this paragraph (t).

(5) *Application to other entities.* This paragraph (t) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(u) *Community-wide health information systems.* Items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that—

(1) The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(2) The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

(v) *Electronic prescribing items and services.* Nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice (as defined at § 411.352) to a physician who is a

member of the group (as defined at § 411.351); or

(iii) PDP sponsor or MA organization to a prescribing physician.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor's cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(w) *Electronic health records items and services.* Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the following conditions are met:

(1) The items and services are provided to a physician by an entity (as defined at § 411.351) that is not a laboratory company.

(2) The software is interoperable (as defined at § 411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to certification criteria identified in the then-applicable version of 45 CFR part 170.

(3) [Reserved]

(4)(i) Before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services.

(ii) Except as provided in paragraph (w)(4)(i) of this section, with respect to items and services received from the donor after the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services at reasonable intervals.

(iii) The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph (w), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);

(ii) The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the physician practices medicine;

(iv) The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the physician; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) [Reserved]

(9) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

(x) *Assistance to compensate a nonphysician practitioner.* (1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services, if all of the following conditions are met:

(i) The arrangement—

(A) Is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner; and

(B) Commences before the physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) enters into the compensation arrangement described in paragraph (x)(1)(vi)(A) of this section.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's NPP referrals to the hospital.

(iii) The remuneration from the hospital—

(A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and

(B) Is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by—

(*1*) Referrals by the physician (or any physician in the physician's practice) or other business generated between the parties; or

(*2*) NPP referrals by the nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the NPP patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under § 411.354(c))—

(A) Furnished NPP patient care services in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide NPP patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished NPP patient care services at the medical practice site located in the geographic area served by the hospital.

(vi)(A) The nonphysician practitioner has a compensation arrangement directly with the physician or the physician organization in whose shoes the physician stands under § 411.354(c); and

(B) Substantially all of the NPP patient care services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide NPP patient care services in the geographic area served by the hospital.

(2) Records of the actual amount of remuneration provided under paragraph (x)(1) of this section by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(3) For purposes of this paragraph (x), ''nonphysician practitioner'' means a physician assistant as defined in section 1861(aa)(5) of the Act, a nurse practitioner or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, a certified nurse-midwife as defined in section 1861(gg) of the Act, a clinical social worker as defined in section 1861(hh) of the Act, or a clinical psychologist as defined at § 410.71(d) of this subchapter.

(4) For purposes of this paragraph (x), the following terms have the meanings indicated.

(i) ''NPP patient care services'' means direct patient care services furnished by a nonphysician practitioner that address the medical needs of specific patients or any task performed by a nonphysician practitioner that promotes the care of patients of the physician or physician organization with which the nonphysician practitioner has a compensation arrangement.

(ii) ''NPP referral'' means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but does not include any designated health service personally performed or provided by the nonphysician practitioner.

(5) For purposes of paragraph (x)(1) of this section, ''geographic area served by the hospital'' has the meaning set forth in paragraph (e)(2) of this section.

(6) For purposes of paragraph (x)(1) of this section, a ''compensation arrangement'' between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) and a nonphysician practitioner—

(i) Means an employment, contractual, or other arrangement under which remuneration passes between the parties; and

(ii) Does not include a nonphysician practitioner's ownership or investment interest in a physician organization.

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, or rural health clinic only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, or rural health clinic to a physician to compensate a nonphysician practitioner to provide NPP patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide NPP patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(ii) The ''geographic area served'' by a federally qualified health center or a rural health clinic has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) *Timeshare arrangements.* Remuneration provided under an arrangement for the use of premises, equipment, personnel, items, supplies, or services if the following conditions are met:

(1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.

(2) The arrangement is between a physician (or the physician organization

in whose shoes the physician stands under § 411.354(c)) and—

(i) A hospital; or

(ii) Physician organization of which the physician is not an owner, employee, or contractor.

(3) The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used—

(i) Predominantly for the provision of evaluation and management services to patients; and

(ii) On the same schedule.

(4) The equipment covered by the arrangement is—

(i) Located in the same building where the evaluation and management services are furnished;

(ii) Not used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient's evaluation and management visit; and

(iii) Not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

(5) The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

(6) The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(7) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(8) [Reserved]

(9) The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

(z) *Limited remuneration to a physician.* (1) Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of $5,000 per calendar year, as adjusted for inflation in accordance with paragraph (z)(3) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(ii) The compensation does not exceed the fair market value of the items or services.

(iii) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(v) Compensation for the use of premises or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises or equipment covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises or equipment covered by the arrangement to the party to which the permission is granted.

(vi) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(2) A physician may provide items or services through employees whom the physician has hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice).

(3) The annual aggregate remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–U for the 12-month period and the new remuneration limit on the physician self-referral website at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp*.

(aa) *Arrangements that facilitate value-based health care delivery and payment*—(1) *Full financial risk*—Remuneration paid under a value-based arrangement, as defined at § 411.351, if the following conditions are met:

(i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

(ii) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(iii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(iv) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(v) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(vi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(vii) For purposes of this paragraph (aa), ''full financial risk'' means that the value-based enterprise is financially responsible on a prospective basis for

the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For purposes of this paragraph (aa), ''prospective basis'' means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.

(2) *Value-based arrangements with meaningful downside financial risk to the physician*—Remuneration paid under a value-based arrangement, as defined at § 411.351, if the following conditions are met:

(i) The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.

(ii) A description of the nature and extent of the physician's downside financial risk is set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(ix) For purposes of this paragraph (aa), ''meaningful downside financial risk'' means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

(3) *Value-based arrangements.* Remuneration paid under a value-based arrangement, as defined at § 411.351, if the following conditions are met:

(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—

(A) The value-based activities to be undertaken under the arrangement;

(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;

(C) The target patient population for the arrangement;

(D) The type or nature of the remuneration;

(E) The methodology used to determine the remuneration; and

(F) The outcome measures against which the recipient of the remuneration is assessed, if any.

(ii) The outcome measures against which the recipient of the remuneration is assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support.

(iii) Any changes to the outcome measures against which the recipient of the remuneration will be assessed are made prospectively and set forth in writing.

(iv) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(v) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(vi) The arrangement is commercially reasonable.

(vii)(A) No less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, the value-based enterprise or one or more of the parties monitor:

(*1*) Whether the parties have furnished the value-based activities required under the arrangement;

(*2*) Whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise; and

(3) Progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed.

(B) If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. Following completion of monitoring that identifies an ineffective value-based activity, the value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise—

(*1*) For 30 consecutive calendar days after completion of the monitoring, if the parties terminate the arrangement; or

(*2*) For 90 consecutive calendar days after completion of the monitoring, if the parties modify the arrangement to terminate the ineffective value-based activity.

(C) If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

(viii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(ix) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(x) If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(xi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(xii) For purposes of this paragraph (aa)(3), ''outcome measure'' means a benchmark that quantifies:

(A) Improvements in or maintenance of the quality of patient care; or

(B) Reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.

(bb) *Cybersecurity technology and related services.* (1) Nonmonetary remuneration (consisting of technology and services) necessary and used predominantly to implement, maintain, or reestablish cybersecurity, if all of the following conditions are met:

(i) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.

(ii) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(iii) The arrangement is documented in writing.

(2) For purposes of this paragraph (bb), ''technology'' means any software or other types of information technology.

■ 3. Effective January 1, 2022, § 411.352 is further amended by revising paragraph (i) to read as follows:

§ 411.352 Group practice.

* * * * *

(i) *Special rules for profit shares and productivity bonuses*—(1) *Overall profits.* (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a share of overall profits that is not directly related to the volume or value of the physician's referrals.

(ii) Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.

(iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to directly relate to the volume or value of referrals if one of the following conditions is met:

(A) Overall profits are divided per capita (for example, per member of the group or per physician in the group).

(B) Overall profits are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(2) *Productivity bonuses.* (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services ''incident to'' such personally performed services, that is not directly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of the physician's referrals if the referrals are for services ''incident to'' the physician's personally performed services).

(ii) A productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician.

(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(3) *Value-based enterprise participation.* Notwithstanding paragraph (g) of this section, profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined at § 411.351, may be distributed to the participating physician.

(4) *Supporting documentation.* Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

Dated: Novemeber 19, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–26140 Filed 11–20–20; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 85 Wednesday,

No. 232 December 2, 2020

Part III

Department of Health and Human Services

Office of Inspector General

42 CFR Parts 1001 and 1003

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001 and 1003

RIN 0936–AA10

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule amends the safe harbors to the Federal anti-kickback statute by adding new safe harbors and modifying existing safe harbors that protect certain payment practices and business arrangements from sanctions under the anti-kickback statute. This rule is issued in conjunction with the Department of Health and Human Services' (HHS's) Regulatory Sprint to Coordinated Care and focuses on care coordination and value-based care. This rule also amends the civil monetary penalty (CMP) rules by codifying a revision to the definition of ''remuneration'' added by the Bipartisan Budget Act of 2018 (Budget Act of 2018).

DATES: These regulations are effective January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Stewart Kameen or Samantha Flanzer, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Social Security Act citation	United States Code citation
1128B, 1128D, 1102, 1128A.	42 U.S.C. 1320a–7b, 42 U.S.C. 1320a–7d, 42 U.S.C. 1302, 42 U.S.C. 1320a–7a.

I. Executive Summary

A. Purpose of the Regulatory Action

The Secretary of HHS (the Secretary) has identified transforming the U.S. health care system to one that pays for value as a top priority. Unlike the traditional fee-for-service (FFS) payment system, which rewards providers for the volume of care delivered, a value-driven health care system is one that pays for health and outcomes. Delivering better value from the health care system will require the transformation of established practices and enhanced collaboration among providers and other individuals and entities. The purpose of this rulemaking is to finalize modifications to existing safe harbors to the Federal anti-kickback statute and finalize the addition of new safe harbors and a new exception to the civil monetary penalty provision prohibiting inducements to beneficiaries, ''Beneficiary Inducements CMP,'' to remove potential barriers to more effective coordination and management of patient care and delivery of value-based care.

The Department launched the Regulatory Sprint with the express purpose of removing potential regulatory barriers to care coordination and value-based care created by certain key health care laws and associated regulations, including the Federal anti-kickback statute and Beneficiary Inducements CMP.[1] Through the Regulatory Sprint, HHS aims to encourage and improve patients' experience of care, providers' coordination of care, and information sharing to facilitate efficient care and preserve and protect patients' access to data.

The Federal anti-kickback statute is an intent-based, criminal statute that prohibits intentional payments, whether monetary or in-kind, in exchange for referrals or other Federal health care program business. Safe harbor regulations describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute. Compliance with a safe harbor is voluntary. The Beneficiary Inducements CMP is a civil, administrative statute that prohibits knowingly offering something of value to a Medicare or State health care program beneficiary to induce them to select a particular provider, practitioner, or supplier.

Stakeholders have raised concerns that these statutes have chilling effect on innovation and value-based care because arrangements in which providers and others coordinate the care of patients with other providers, share resources among themselves to facilitate better care coordination, share in the benefits of more efficient care delivery, and engage and support patients can implicate these statutes.

B. The Proposed Rule

On October 17, 2019, OIG published a notice of proposed rulemaking[2] (OIG Proposed Rule) to add or amend various regulatory protections under the Federal anti-kickback statute and Beneficiary Inducements CMP with the goal of proposing protections for certain value-based arrangements that would improve quality, outcomes, and efficiency. The proposals focused on arrangements to advance the coordination and management of patient care, with an aim to support innovative methods and novel arrangements, including the use of digital health technology such as remote patient monitoring and telehealth. We proposed safe harbors for value-based arrangements where the parties assume full financial risk, substantial downside financial risk, and no or lower risk. The proposed safe harbors offered more flexibility for arrangements where the parties assumed more financial risk. Consistent with OIG's law enforcement mission and section 1128D(a)(2)(I) of the Act, the proposals included safeguards tailored to protect Federal health care programs and beneficiaries from the risks of fraud and abuse associated with kickbacks, such as overutilization and inappropriate patient steering, as well as risks associated with risk-based payment mechanisms, such as stinting on care.

The OIG Proposed Rule proposed new terminology to define the universe of value-based arrangements that could qualify for the new safe harbors, proposing to require that providers, suppliers, practitioners, and others would form value-based enterprises (VBEs) to collaborate to achieve value-based purposes, such as coordinating and managing a target patient population, improving quality of care for a target patient population, and reducing costs. VBEs could be large or small. VBEs could be formal corporate structures or looser affiliations. Under the proposed definition, VBEs would be required to have an accountable body and transparent governance. We proposed that some types of entities would not be eligible to use the value-based safe harbors because of heightened fraud risk and because the entities did not play a central, frontline role in coordinating and managing patient care.

[1] The Federal anti-kickback statute is codified at 42 U.S.C. 1320a–7b(b); the Beneficiary Inducements CMP is codified at 42 U.S.C. 1320a–7a(a)(5). Additionally, the Regulatory Sprint includes the physician self-referral law, 42 U.S.C. 1395nn, 42 CFR part 2, and provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

[2] 84 FR 55694 (Oct. 17, 2019). In connection with the Regulatory Sprint, and to help develop the proposals in the OIG Proposed Rule, OIG published a Request for Information (OIG RFI) seeking input on new or modified safe harbors to promote care coordination and value-based care and protect patients and taxpayer dollars from harms cause by fraud and abuse. 83 FR 43607 (Aug. 27, 2018).

The OIG Proposed Rule proposed to modify existing safe harbors that advance coordinated care for patients, including information sharing. OIG proposed modifications to existing safe harbors for local transportation, electronic health records arrangements, and personal services and management contracts. Further, the OIG Proposed Rule proposed new protections for outcomes-based payments, cybersecurity technology and services arrangements, remuneration in connection with CMS-sponsored models (largely supplanting the need for separate OIG fraud and abuse waivers for these models), telehealth technologies for in-home dialysis patients (statutory), and Medicare Shared Savings Program ACO beneficiary incentives (statutory). For each new safe harbor or exception, OIG proposed a set of conditions designed to ensure that the safe harbor or exception protected beneficial arrangements and reduced risks of fraud and abuse.

Taken as a whole, the OIG Proposed Rule proposed significant new flexibilities for value-based arrangements and modernization of the safe harbor regulations to account for the ongoing evolution of the health care delivery system. OIG developed its proposals in coordination with the Centers for Medicare & Medicaid Services (CMS), which concurrently issued proposed regulations in connection with the Regulatory Sprint (CMS NPRM).[3] OIG solicited comments on the wide range of issues raised by the proposals. We received 337 timely comments, 327 of which were unique, from a broad range of stakeholders.

C. The Final Rule

We are finalizing the proposed new and modified anti-kickback statute safe harbors and exception to the Beneficiary Inducements CMP, with modifications and clarifications explained in the preamble to this rule. Stakeholder reaction was largely positive, although many commenters raised concerns and expressed preferences about specific provisions. Some commenters raised concerns about potential risks of fraud and impacts on competition.

In this final rule, we sought to strike the right balance between flexibility for beneficial innovation and better coordinated patient care with necessary safeguards to protect patients and Federal health care programs. Many beneficial arrangements do not implicate the anti-kickback statute and do not need protection. For example, the parties may be exchanging nothing of value between them or the arrangements might involve no Federal health care program patients or business. Other beneficial arrangements might implicate the statute (for example, the arrangement might involve parties that are exchanging something of value and are in a position to refer Federal health care program business between them) but will not fit in these or other available safe harbors. Arrangements are not necessarily unlawful because they do not fit in a safe harbor. Arrangements that do not fit in a safe harbor are analyzed for compliance with the Federal anti-kickback statute based on the totality of their facts and circumstances, including the intent of the parties. Some care coordination and value-based arrangements can be structured to fit in existing safe harbors.

Flexibilities to engage in new business, care delivery, and digital health technology arrangements with lowered compliance risk may assist industry stakeholders in their response to and recovery from the current public health emergency resulting from the novel coronavirus disease 2019 (COVID–19) pandemic. The final rule may also help providers and others develop sustainable value-based care delivery models for the future.

1. Final Anti-Kickback Statute Safe Harbors

We are finalizing the following regulations, as explained in section III of this preamble.

Terminology and Framework. We are finalizing, with modifications, the proposed terminology that describes VBEs and VBE participants eligible to use the value-based safe harbors and the tiered framework of three value-based safe harbors that vary based on the level of risk assumed by the parties, with more flexibility associated with assumption of more risk. See section III.2.1–2 for further discussion.

Safe Harbors for Value-Based Arrangements. We are finalizing, with modifications, three new safe harbors for remuneration exchanged between or among participants in a value-based arrangement (as further defined) that fosters better coordinated and managed patient care:

(i) Care coordination arrangements to improve quality, health outcomes, and efficiency (paragraph 1001.952(ee)) without requiring the parties to assume risk;

(ii) value-based arrangements with substantial downside financial risk (paragraph 1001.952(ff)); and,

(iii) value-based arrangements with full financial risk (paragraph 1001.952(gg)).

These safe harbors address a broad range of potential value-based arrangements for care coordination activities, including use of digital health technology. We discuss each safe harbor in more detail in section III.B.3–5. The value-based safe harbors vary, among other ways, by the types of remuneration protected (in-kind or in-kind and monetary), the types of entities eligible to rely on the safe harbors, the level of financial risk assumed by the parties, and the types of safeguards included as safe harbor conditions. By design, these safe harbors offer flexibility for innovation and customization of value-based arrangements to the size, resources, needs, and goals of the parties to them. The safe harbors allow for emerging arrangements that reflect up-to-date understandings in medicine, science, and technology.

These three new safe harbors are not the exclusive, available safe harbors for care coordination or value-based arrangements. All three value-based safe harbors offer protection for in-kind remuneration, such as technology or services. However, only the safe harbors for value-based arrangements with substantial assumption of risk (paragraphs 1001.952(ff) and (gg)) protect monetary remuneration. The care coordination arrangements safe harbor at paragraph 1001.952(ee), which requires little or no assumption of risk, does not. However, parties to arrangements involving monetary remuneration, such as shared savings or performance bonus payments, may be eligible for the new protection for outcomes-based payments at paragraph 1001.952(d)(2). Parties to arrangements under CMS-sponsored models may prefer to look to the new safe harbor specifically for those models at paragraph 1001.952(ii).

As explained at section III.B.2.e below, entities ineligible to use the value-based safe harbors are: Pharmaceutical manufacturers, distributors, and wholesalers; pharmacy benefit managers (PBMs); laboratory companies; pharmacies that primarily compound drugs or primarily dispense compounded drugs; manufacturers of devices or medical supplies; entities or individuals that sell or rent durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); and medical device distributors and wholesalers. However, the care coordination arrangements safe harbor includes a separate pathway, with specific conditions, that protects digital technology arrangements (as

[3] 84 FR 55766 (Oct. 17, 2019).

defined at paragraph 1001.952(ee)(14)) involving manufacturers of devices or medical supplies and DMEPOS.

Patient Engagement and Support Safe Harbor. We are finalizing, with modifications, a new safe harbor (paragraph 1001.952(hh)) for patient engagement tools and supports furnished by a participant in a value-based enterprise to a patient in a target patient population (discussed in section III.B.6). This safe harbor uses the same ineligible entities list as the value-based safe harbors, above, but includes a pathway for manufacturers of devices or medical supplies to provide digital health technology.

CMS-Sponsored Models Safe Harbor. We are finalizing, with modifications, a new safe harbor (paragraph 1001.952(ii)) for CMS-sponsored model arrangements and CMS-sponsored model patient incentives that would require OIG fraud and abuse waivers. This safe harbor (discussed at section III.B.7) is intended to provide greater predictability model participants and uniformity across models. It will reduce the need for separate OIG fraud and abuse waivers for new CMS-sponsored models.

Cybersecurity Technology and Services Safe Harbor. We are finalizing, with modifications, a new safe harbor (paragraph 1001.952(jj)) for remuneration in the form of cybersecurity technology and services (discussed at section III.B.8). This safe harbor will facilitate improved cybersecurity in health care and is available to all types of individuals and entities.

Electronic Health Records Safe Harbor. We are finalizing our proposal to modify the existing safe harbor for electronic health records items and services (paragraph 1001.952(y)). We are finalizing, with modifications, changes to update and remove provisions regarding interoperability, remove the sunset provision and prohibition on donation of equivalent technology, and clarify protections for cybersecurity technology and services included in an electronic health records arrangement (discussed at section III.B.9).

Personal Services and Management Contracts and Outcomes-Based Payments. We are finalizing our proposal to modify the existing safe harbor for personal services and management contracts (paragraph 1001.952(d)(1)). We are finalizing, without modification, changes to increase flexibility for part-time or sporadic arrangements and arrangements for which aggregate compensation is not known in advance. We are also a finalizing, with modifications, new protection for outcomes-based payments (paragraph 1001.952(d)(2)). These changes are discussed at section III.B.10. The new safe harbor for outcomes-based payments protects payments tied to achieving measurable outcomes that improve patient or population health or appropriately reduce payor costs. It makes ineligible the same entities that are ineligible for the value-based safe harbors.

Warranties. We are finalizing our proposal to modify the existing safe harbor for warranties (paragraph 1001.952(g)). We are finalizing, without modification, revisions to the definition of ''warranty'' and to provide protection for warranties for one or more items and related services (discussed at section III.B.11). This safe harbor is available to any type of entity.

Local Transportation. We are finalizing our proposal to modify the existing safe harbor for local transportation furnished to beneficiaries (paragraph 1001.952(bb)). We are finalizing, with modifications, changes to expand mileage limits for rural areas (up to 75 miles) and eliminate mileage limits for transportation to convey patients discharged from the hospital to their place of residence (discussed at section III.B.12). We also clarify that the safe harbor is available for transportation provided through rideshare arrangements.

ACO Beneficiary Incentives. We are codifying, without modification to our proposal, the statutory exception to the definition of ''remuneration'' at section 1128B(b)(3)(K) of the Act related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program (paragraph 1001.952(kk)) (discussed at section III.B.13).

2. Beneficiary Inducements CMP

The final rule amends the Beneficiary Inducements CMP regulations at 42 CFR 1003 as follows:

Telehealth Technologies for In-Home Dialysis Patients. We are codifying the statutory exception for ''telehealth technologies'' furnished to certain in-home dialysis patients, pursuant to section 50302(c) of the Budget Act of 2018 (discussed at section III.C.1). We are finalizing our proposal with modifications.

By operation of law, arrangements that fit in the new and modified Federal anti-kickback statute safe harbors for patient engagement and support, paragraph 1001.952(hh), and local transportation, paragraph 1001.952(bb), are also protected under the Beneficiary Inducements CMP.

II. Background

A. Purpose and Need for Regulatory Action

HHS's Regulatory Sprint aims to remove potential regulatory barriers to care coordination and value-based care created by four key health care laws and associated regulations: (i) The physician self-referral law, (ii) the Federal anti-kickback statute, (iii) the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[4] and (iv) rules under 42 CFR part 2 related to substance use disorder treatment.

Through the Regulatory Sprint, HHS aims to encourage and improve:

- A patient's ability to understand treatment plans and make empowered decisions;
- providers' alignment on end-to-end treatment (*i.e.,* coordination among providers along the patient's full care journey);
- incentives for providers to coordinate, collaborate, and provide patients tools and supports to be more involved in their own care; and
- information sharing among providers, facilities, and other stakeholders in a manner that facilitates efficient care while preserving and protecting patient access to data.

Since the enactment in 1972 of the Federal anti-kickback statute, there have been significant changes in the delivery of, and payment for, health care items and services both within the Medicare and Medicaid programs and also for non-Federal payors and patients. Such changes include modifications to traditional FFS Medicare (*i.e.,* Medicare Parts A and B), Medicare Advantage, and States' Medicaid programs. The Department has a longstanding commitment to aligning Medicare payment with quality of care delivered to Federal health care program beneficiaries.

The Department identified the broad reach of the Federal anti-kickback statute[5] and the CMP law provision prohibiting inducements to beneficiaries, the ''Beneficiary Inducements CMP''[6] as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care among providers and across care settings in both the Federal health care programs and commercial sectors.

[4] Public Law 104–191, 110 Stat. 1936.

[5] 42 U.S.C. 1320a–7b(b).

[6] 42 U.S.C. 1320a–7a(a)(5).

B. Federal Anti-Kickback Statute and Safe Harbors

Section 1128B(b) of the Act, (42 U.S.C. 1320a–7b(b), the anti-kickback statute), provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act (42 U.S.C. 1320a–7b(f)). The offense is classified as a felony and is punishable by fines of up to $100,000 and imprisonment for up to 10 years. Violations of the Federal anti-kickback statute also may result in the imposition of CMPs under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729–33).

The types of remuneration covered specifically include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients but also the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any Federal health care program.

Because of the broad reach of the statute and concerns that some relatively innocuous business arrangements were covered by the statute and therefore potentially subject to criminal prosecution, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93 (note to section 1128B of the Act; 42 U.S.C. 1320a–7b). This provision specifically requires the development and promulgation of regulations, the so-called safe harbor provisions, that would specify various payment and business practices that would not be subject to sanctions under the anti-kickback statute, even though they potentially may be capable of inducing referrals of business for which payment may be made under a Federal health care program.

Section 205 of HIPAA established section 1128D of the Act (42 U.S.C. 1320a–7d), which includes criteria for modifying and establishing safe harbors. Specifically, section 1128D(a)(2) of the Act provides that, in modifying and establishing safe harbors, the Secretary may consider whether a specified payment practice may result in:

- An increase or decrease in access to health care services;
- an increase or decrease in the quality of health care services;
- an increase or decrease in patient freedom of choice among health care providers;
- an increase or decrease in competition among health care providers;
- an increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations;
- an increase or decrease in costs to Federal health care programs;
- an increase or decrease in the potential overutilization of health care services;
- the existence or nonexistence of any potential financial benefit to a health care professional or provider, which benefit may vary depending on whether the health care professional or provider decides to order a health care item or service or arranges for a referral of health care items or services to a particular practitioner or provider; or
- any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs.

In giving the Department the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the health care industry.[7] Since July 29, 1991, there have been a series of final regulations published in the **Federal Register** establishing safe harbors in various areas.[8] These safe harbor provisions have been developed to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements.[9]

Health care providers and others may voluntarily seek to comply with final safe harbors so that they have the assurance that their business practices would not be subject to any anti-kickback enforcement action. Compliance with an applicable safe harbor insulates an individual or entity from liability under the Federal anti-kickback statute and the Beneficiary Inducements CMP only; individuals and entities remain responsible for complying with all other laws, regulations, and guidance that apply to their businesses.

C. Civil Monetary Penalty Authorities

1. Overview of OIG Civil Monetary Penalty Authorities

In 1981, Congress enacted the CMP law, section 1128A of the Act, 42 U.S.C. 1320a–7a, as one of several administrative remedies to combat fraud and abuse in Medicare and Medicaid. The law authorized the Secretary to impose penalties and assessments on persons who defrauded Medicare or Medicaid or engaged in certain other wrongful conduct. The CMP law also authorized the Secretary to exclude persons from Federal health care programs (as defined in section 1128B(f) of the Act, 42 U.S.C. 1320a–7b(f)) and to direct the appropriate State agency to exclude the person from participating in any State health care programs (as defined in section 1128(h) of the Act, 42 U.S.C. 1320a–7(h)). Congress later expanded the CMP law and the scope of exclusion to apply to all Federal health care programs, but the CMP applicable to beneficiary inducements remains limited to Medicare and State health care program beneficiaries. Since 1981, Congress has created various other CMP authorities covering numerous types of fraud and abuse.

2. The Definition of ''Remuneration''

Section 1128A(a)(5) of the Act, 42 U.S.C. 1320a–7a(a)(5), the ''Beneficiary Inducements CMP,'' provides for the

[7] H.R. Rep. No. 100–85, Pt. 2, at 27 (1987).

[8] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952 (July 29, 1991); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans, 61 FR 2122 (Jan. 25, 1996); Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 FR 63504 (Nov. 19, 1999); Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 FR 63518 (Nov. 19, 1999); 64 FR 63504 (Nov. 19, 1999); Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute, 66 FR 62979 (Dec. 4, 2001); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 FR 45109 (Aug. 8, 2006); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 FR 56632 (Oct. 4, 2007); Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 FR 79202 (Dec. 27, 2013); and Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 FR 88368 (Dec. 7, 2016).

[9] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR at 35958 (July 21, 1991).

imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). Section 1128A(i)(6) of the Act, 42 U.S.C. 1320a–7a(i)(6), defines ''remuneration'' for purposes of the Beneficiary Inducements CMP as including transfers of items or services for free or for other than fair market value. Section 1128A(i)(6) of the Act also includes a number of exceptions to the definition of ''remuneration.''

Pursuant to section 1128A(i)(6)(B) of the Act, any practice permissible under the anti-kickback statute, whether through statutory exception or safe harbor regulations issued by the Secretary, is also excepted from the definition of ''remuneration'' for purposes of the Beneficiary Inducements CMP. However, no parallel exception exists in the anti-kickback statute. Thus, the exceptions in section 1128A(i)(6) of the Act apply only to the definition of ''remuneration'' applicable to section 1128A.

Relevant to this rulemaking, the Budget Act of 2018 created a new exception to the definition of ''remuneration'' for purposes of the Beneficiary Inducements CMP. This statutory exception applies to ''telehealth technologies'' provided on or after January 1, 2019, by a provider of services or a renal dialysis facility to an individual with end stage renal disease (ESRD) who is receiving home dialysis for which payment is being made under Medicare Part B.

D. Summary of the OIG Proposed Rule

On October 17, 2019, OIG published a proposed rule in the **Federal Register** (84 FR 55694) setting forth certain proposed amendments to the safe harbors under the anti-kickback statute and a proposed amendment to the Beneficiary Inducements CMP exceptions (the OIG Proposed Rule). With respect to the anti-kickback statute, we proposed seven new safe harbors and modifications to four existing safe harbors. Specifically, we proposed new protection for:

- A safe harbor for care coordination arrangements to improve quality, health outcomes, and efficiency (1001.952(ee));
- A safe harbor for value-based arrangements with substantial downside financial risk (1001.952(ff));
- A safe harbor for value-based arrangements with full financial risk (1001.952(gg));
- A safe harbor for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency (1001.952(hh));
- A safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (1001.952(ii));
- A safe harbor for cybersecurity technology and related services (1001.952(jj)); and
- A safe harbor that would codify the statutory exception to the definition of ''remuneration'' at section 1128B(b)(3)(K) of the Act related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program (1001.952(kk)).
- An exception to the Beneficiary Inducements CMP for telehealth technologies for in-home dialysis patients (1003.110).

We proposed to modify:

- The safe harbor for personal services and management contracts and outcomes-based payment arrangements (1001.952(d));
- The safe harbor for warranties (1001.952(g));
- The safe harbor for electronic health records items and services (1001.952(y)); and
- The safe harbor for local transportation (1001.952(bb)).

An overarching goal of our proposals was to develop final rules that protect low-risk, beneficial arrangements without opening the door to fraudulent or abusive conduct that increases Federal health care program costs or compromises quality of care for patients or patient choice. We solicited comments on our proposed policies to obtain the benefit of public input from affected stakeholders.

Our proposals are summarized in greater detail in section III of this preamble, organized by topic, along with summaries of the final decisions, and summaries of the related comments and our responses.

E. Summary of the Final Rulemaking

In this final rule, we modify existing as well as add new safe harbors pursuant to our authority under section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 by specifying certain payment practices that will not be subject to prosecution under the anti-kickback statute. We intend to protect practices that pose a low risk to Federal health care programs and beneficiaries, as long as specified conditions are met. In doing so, we considered the factors cited by Congress in granting statutory authority to the Secretary under Section 1128D(a)(2) of the Social Security Act.[10] Specifically, the new and modified safe harbors are designed to further the goals of access, quality, patient choice, appropriate utilization, and competition, while protecting against increased costs, inappropriate steering of patients, and harms associated with inappropriate incentives tied to referrals. We also codify into our regulations a statutory safe harbor for patient incentives offered by accountable care organizations (ACOs) to assigned beneficiaries under ACO Beneficiary Incentive Programs and an exception to the definition of ''remuneration'' in 42 CFR 1003.110 for certain telehealth technologies for in-home dialysis.

To facilitate review of the new and modified safe harbors and exception in context, we summarize the proposals and final regulations by topic in section III.B below. The following are the safe harbors and the exception that we are finalizing, together with the citation to where they appear in our regulations and a reference to the preamble section of this final rule where they are discussed in greater detail:

- Modifications to the existing safe harbor for personal services and management contracts, including outcomes-based payments, at paragraph 1001.952(d) (preamble section III.B.10);
- modifications to the existing safe harbor for warranties at paragraph 1001.952(g) (preamble section III.B.11);
- modifications to the existing safe harbor for electronic health records items and services at paragraph 1001.952(y) (preamble section III.B.9);
- modifications to the existing safe harbor for local transportation at paragraph 1001.952(bb) (preamble section III.B.12)
- a new safe harbor for care coordination arrangements to improve quality, health outcomes, and efficiency at paragraph 1001.952(ee) (preamble sections III.B.1, III.B.2, and III.B.3);
- a new safe harbor for value-based arrangements with substantial downside financial risk at paragraph 1001.952(ff) (preamble sections III.B.1, III.B.2, and III.B.4);
- a new safe harbor for value-based arrangements with full financial risk at paragraph 1001.952(gg) (preamble sections III.B.1, III.B.2, and III.B.5);
- a new safe harbor for arrangements for patient engagement and support to improve quality, health outcomes, and

[10] 42 U.S.C. 1320a–7d(a)(2).

efficiency at paragraph 1001.952(hh) (preamble section III.B.6);

- a new safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives at paragraph 1001.952(ii) (preamble section III.B.7);
- a new safe harbor for cybersecurity technology and related services at paragraph 1001.952(jj) (preamble section III.B.8);
- a new safe harbor for accountable care organization (ACO) beneficiary incentive program at paragraph 1001.952(kk) (preamble section III.B.13); and
- an exception for telehealth technologies for in-home dialysis at paragraph 1003.110 (preamble section III.C.1)

III. Summary of Final Provisions, Public Comments, and OIG Responses

A. General

OIG received 337 comments, 327 of which were unique, in response to the OIG Proposed Rule. A range of individuals and entities submitted these comments, including: Physicians and other types of clinicians, hospitals and health systems, other health care providers (*e.g.,* post-acute providers, laboratories, durable medical equipment suppliers, and dialysis providers), accountable care organizations, pharmaceutical and medical device manufacturers, health technology entities, pharmacies, third-party payors, trade associations, law firms, and consumer and patient advocacy groups.

As a general matter, most commenters strongly supported the proposed safe harbors and the need for regulatory reform to the safe harbors and exceptions to the definition of ''remuneration'' under the Beneficiary Inducements CMP. While the majority of commenters recommended various revisions to the proposed safe harbors to increase regulatory flexibility, some commenters acknowledged that increased regulatory flexibility could increase the risk of harms associated with fraud and abuse and recommended revisions to add or strengthen safeguards in the safe harbor proposals. A few did not support the proposed safe harbor protections for value-based arrangements as proposed in paragraphs 1001.952(ee), (ff), (gg), primarily citing fraud and abuse risks. We have considered these comments carefully in developing the final rule, as described in more detail in responses to comments.

1. Alignment With CMS

Several of the final safe harbors intersect with the physician self-referral law exceptions that CMS is finalizing as part of the Regulatory Sprint: The three new safe harbors for value-based arrangements at paragraphs 1001.952(ee), (ff), and (gg), the new cybersecurity safe harbor at paragraph 1001.952(jj), and the modifications to the electronic records safe harbor at paragraph 1001.952(y).

Comment: We received comments asking OIG and CMS to align our final rules in connection with the Regulatory Sprint to the greatest extent possible. Some commenters believed that the CMS and OIG proposals would perpetuate a dual regulatory environment (where, *e.g.,* an arrangement could potentially violate one law but meet the requirements for protection under the other) and that a lack of consistency would make it more challenging for entities to navigate an already-complex regulatory framework. Some commenters suggested that the OIG Proposed Rule was too narrow compared to the CMS NPRM and requested that OIG protect what they described as a broader universe of arrangements that would be protected under the CMS proposals. Another commenter asked that OIG clarify in the final rule that compliance with the physician self-referral law would rebut any implication of intent under Federal anti-kickback statute.

Response: We are mindful of reducing burden on providers and other industry stakeholders, and we have sought to align value-based terminology and safe harbor conditions with those being adopted by CMS in its physician self-referral regulations as part of the Regulatory Sprint wherever possible (CMS Final Rule).[11] However, complete alignment is not feasible because of fundamental differences in statutory structures and sanctions across the two laws. As aforementioned, the Federal anti-kickback statute is an intent-based, criminal statute that covers all referrals of Federal health care program business (including, but not limited to, physician referrals). In contrast, the physician self-referral law is a civil, strict-liability statute that prohibits payment by CMS for a more limited set of services referred by physicians who have certain financial relationships with the entity furnishing the services. As a result, the value-based exceptions adopted by CMS do not need to contemplate the broad range of conduct that implicates the Federal anti-kickback statute.

Federal anti-kickback statute safe harbors and physician self-referral law exceptions also operate differently. Because the physician self-referral law is a strict-liability statute, when an arrangement implicates the law, compliance with an exception is the only option to avoid overpayment liability. In other words, the exceptions define the full universe of acceptable arrangements that implicate the physician self-referral law. Even minor or erroneous deviations from the specific terms of a physician self-referral law exception can result in non-compliance and, because of the statute's strict liability, overpayments. In contrast, compliance with an anti-kickback statute safe harbor is voluntary, and there are many arrangements that do not fit in a safe harbor that are lawful under the anti-kickback statute. Deviating from a safe harbor does not mean that an arrangement violates the anti-kickback statute. For arrangements that do not fit in a safe harbor, liability is determined based on the totality of facts and circumstances, including the intent of the parties.

Because the Federal anti-kickback statute is not a strict liability law, the value-based safe harbors we are adopting need not capture the full universe of value-based arrangements that are legal under the Federal anti-kickback statute in order to accomplish the goals of removing barriers to more effective coordination and management of patient care. Thus, in designing our safe harbors, rather than mirror CMS's exceptions, we have included safe harbor conditions designed to ensure that protected arrangements are not disguised kickback schemes. We recognize that, for purposes of those arrangements that implicate both the physician self-referral law and the Federal anti-kickback statute, the value-based safe harbors may therefore protect a narrower universe of such arrangements than CMS's exceptions.

To protect Federal health care programs and beneficiaries, we believe that it is important for the Federal anti-kickback statute to serve as ''backstop'' protection against abusive arrangements that involve the exchange of remuneration intended to induce or reward referrals and that might be protected by the physician self-referral law exceptions. In this way, the OIG and CMS rules, operating together, create pathways for parties entering into value-based arrangements that are subject to both laws to develop and implement value-based arrangements that avoid strict liability for technical noncompliance, while ensuring that the Federal Government can pursue those parties engaging in arrangements that are intentional kickback schemes.

[11] The CMS Final Rule is being published elsewhere in this version of the **Federal Register**.

Further, many requirements of the final safe harbors and exceptions are consistent, particularly in the cybersecurity and electronic health records areas. In addition, the value-based terminology that describes the value-based enterprises and value-based arrangements that are eligible for protection under a value-based safe harbor under the anti-kickback statute or a value-based exception under the physician self-referral law are aligned in nearly all respects, except with respect to the definition of ''value-based activities'' and where slightly different language was required to integrate the new rules into the existing regulatory structures (points of difference are discussed later in this preamble). As a practical matter, this means that the same value-based enterprise or value-based arrangement can seek protection under both regulatory schemes, provided the relevant conditions of a safe harbor and an exception are satisfied.

In sum, because of statutory distinctions, compliance with a value-based safe harbor may require satisfaction of conditions additional to, or different from, those in a corresponding physician self-referral law exception. This is by design. We have endeavored to ensure that an arrangement that fits in a value-based safe harbor has a viable pathway for protection under a physician self-referral law exception. However, an arrangement that fits under a physician self-referral law exception might not fit in an anti-kickback statute safe harbor or might not fit unless additional features are added to the arrangement. That said, it is the Department's belief that compliance with one regulatory structure should not preclude compliance with the other.

We disagree that compliance with the physician self-referral law rebuts any implication of intent under the Federal anti-kickback statute. Indeed, it is possible, depending on the facts and circumstances, that an arrangement may comply with an exception to the physician self-referral law but violate the Federal anti-kickback statute. The fact that a party complies with the requirements of the physician self-referral law is not evidence that the party does or does not have the intent to induce or reward referrals for purposes of the Federal anti-kickback statute. Parties may achieve compliance with an applicable exception to the physician self-referral law regardless of the intent of the parties. In addition, other differences between the physician self-referral law and Federal anti-kickback statute could lead to compliance with the physician self-referral law but not with the Federal anti-kickback statute. For example, parties may conclude that there are no ''referrals,'' as that term is defined for purposes of the physician self-referral law, but such assessment is inconclusive with respect to whether there are referrals, or the requisite intent to induce or reward referrals, for purposes of the Federal anti-kickback statute.

2. Comments Outside the Scope of the Rulemaking

We received some comments that were outside the scope of this rulemaking. In some cases, comments (*e.g.,* a request to update the physician self-referral law's in-office ancillary services exception) were outside the scope of our authority. Other comments and suggestions were outside the scope of this rulemaking but could be considered for future guidance or rulemaking. For example, some commenters urged OIG to modify existing safe harbors or develop entirely new safe harbors that were not related to the safe harbors and modifications proposed in the OIG Proposed Rule (*e.g.,* an amendment to the referral services safe harbor, new safe harbors specific to Indian health care providers, and a new safe harbor specific to value-based contracting with manufacturers for the purchase of pharmaceutical products). Others requested sub-regulatory guidance outside the rule, such as a Frequently Asked Question feature to respond to specific questions or common scenarios from stakeholders. These or other topics that are outside the scope of this particular rulemaking are not summarized or discussed in detail in this final rule.

In the next sections of this preamble, we summarize each proposal from the OIG Proposed Rule (full detail of the proposals can be found at 84 FR 55694); summarize the final rule, including significant changes from the proposals; and respond to public comments.

B. Federal Anti-Kickback Statute Safe Harbors

1. Value-Based Framework for Value-Based Arrangements

Summary of OIG Proposed Rule: We proposed a set of value-based terminology, detailed in the next section, to describe the universe of value-based arrangements that would, as a threshold matter, be eligible to seek safe harbor protection under three safe harbors specific to value-based arrangements between VBEs and one or more of their VBE participants or between or among VBE participants: (i) The care coordination arrangements to improve quality, health outcomes, and efficiency safe harbor at 42 CFR 1001.952(ee), (ii) the value-based arrangements with substantial downside financial risk safe harbor at 42 CFR 1001.952(ff), (iii) and the full financial risk safe harbor at 42 CFR 1001.952(gg) (collectively referred to as the ''value-based safe harbors''). The value-based safe harbors would offer greater flexibilities to parties as they assume more downside financial risk.

We proposed this tiered structure to support the transformation of industry payment systems and in recognition that arrangements involving higher levels of downside financial risk for those in a position to make referrals or order products or services could curb, at least to some degree, FFS incentives to order medically unnecessary or overly costly items and services.

Summary of Final Rule: We are finalizing the tiered value-based framework of three safe harbors that vary based on risk assumption of the parties. Modifications to specific value-based terminology are discussed in the next section.

Comment: Many commenters expressed support for our value-based framework. For example, a commenter stated that OIG had achieved a proper balance between flexibility for beneficial innovation and safeguards to protect patients and Federal health care programs against fraud and abuse risks. Others commended OIG for embracing the transition from no risk to downside financial risk as a central component of the value-based framework. In particular, commenters supported OIG's proposal under the care coordination arrangements safe harbor to afford protection to value-based arrangements in which parties had yet to take on downside financial risk.

Response: We have finalized the value-based framework of three safe harbors, as proposed. We have made modifications to some of the value-based terminology as discussed in Section III.B.2 below. We explain the specific reasons for the modifications to the value-based terminology in responses to comments in section III.B.2.

Comment: Several commenters expressed general support for the proposed value-based safe harbors, while also recommending that OIG proceed with caution. For example, a payor urged us to maintain in the final rule the level of rigor reflected in the proposed value-based safe harbor and not increase the leniency provided under the proposed regulations.

Similarly, a trade association suggested that OIG take a limited ''phased-in'' approach to the safe harbors to facilitate identification of appropriate patient protection and program integrity guardrails. Another commenter recommended that, at least once every 3 years, OIG assess and report on the effects of the value-based safe harbors, *e.g.,* review clinical benefits, analyze cost savings, and solicit stakeholder input. A commenter also cautioned that giving more flexible safe harbor protection to value-based arrangements that include greater risk may push providers into assuming risk before they are ready to do so.

Response: With this final rule, we have sought to find the appropriate balance between the policy goals of the Regulatory Sprint and the need to protect both patients and Federal health care programs. We decline to adopt the commenters' specific recommendations related to a potential phased-in approach or the regular publication of related reports, but we note that we may undertake future reviews of value-based arrangements in Federal health care programs as part of our oversight mission. We have included robust safeguards in the value-based safe harbors to address the commenters' concerns. We note that we are affording greater flexibilities under the substantial downside and full financial risk safe harbors in recognition of parties' assumption of the requisite level of downside financial risk. Others who may not be ready or willing to assume risk, or who are only ready or willing to assume risk at a level below that required by the substantial downside financial risk or full financial risk safe harbors, may look to the care coordination arrangements safe harbor, which does not require the assumption of risk, structure arrangements to fit in another safe harbor that might apply, or enter into arrangements that are not protected by a safe harbor, given that structuring an arrangement to satisfy a safe harbor is voluntary.

Comment: Other commenters expressed concerns about potential fraud and abuse, with several asserting that the value-based safe harbors would foster an environment vulnerable to fraud and anticompetitive effects. Commenters had varying rationales for their position, including, for example, that existing safe harbors would be sufficient to advance value-based models; evaluation was warranted before finalizing these safe harbors; and the care coordination focus of the value-based safe harbors would lead to further industry consolidation. A state health department broadly asserted that the proposals lacked sufficient detail and, if finalized, would pose enforcement challenges. That commenter requested that we add more detail in our rulemaking, rather than through sub-regulatory guidance, to assist the state with developing comprehensive policies to support the rule.

Several radiology trade associations expressed concern that the safe harbors omitted the guiding principle of fair market value and the restriction on determining the amount or nature of the remuneration based on the volume or value of referrals, and consequently, the value-based arrangements could be abused or used as a means for referring providers to pay less for radiology or imaging services. Generally, these commenters supported the creation of value-based safe harbors only to the extent parties to a value-based arrangement had assumed significant downside financial risk. They recommended that each value-based safe harbor include provisions prohibiting referring VBE participants from underpaying for radiology and imaging services within a VBE or otherwise leveraging their ability to direct referrals.

Response: The commenters raise important concerns about potential harms resulting from fraud and abuse; we considered these harms carefully in developing the final rule. In response to comments, throughout this final rule we have clarified regulatory text to minimize confusion; offered additional explanations in preamble to expound upon OIG's interpretation of provisions in the value-based safe harbors; and provided illustrative examples for the value-based terminology, which we believe will aid in both enforcement and compliance. Parties also may request an advisory opinion from OIG to determine whether an arrangement meets the conditions of a safe harbor or is otherwise sufficiently low risk under the Federal anti-kickback statute to receive prospective immunity from administrative sanctions by OIG.

This final rule aims to protect value-based arrangements that enhance patient care and deliver value, and we have included safeguards designed to preclude from protection arrangements that lead to medically unnecessary care, might involve coercive marketing, or limit clinical decision-making. These safeguards are described in greater detail below and throughout this preamble. In addition, certain entities that present heightened program integrity risk and are less likely to be at the front lines of care coordination are not eligible to rely on the value-based safe harbors or subject to additional safeguards. We believe the potential benefits of the final value-based safe harbors (*e.g.,* facilitating the transition to value-based care and encouraging greater care coordination) outweigh the potential risks related to fraud and competition.

The value-based safe harbors, as finalized, do not include the traditional fraud and abuse safeguards of fair market value or a broad prohibition on taking into account the volume or value of any referrals. However, we have included other safeguards in each of the value-based safe harbors that are intended to address potential fraud and abuse risks, *e.g.,* a prohibition on taking into account the volume or value of referrals outside the target patient population, limits on directed referrals, and others described elsewhere in this preamble. The risk sharing required by the substantial downside financial risk and full financial risk safe harbors reduces some fraud and abuse concerns associated with a traditional fee-for-service payment system. We also included safeguards specific to the care coordination arrangements safe harbor, *e.g.,* a contribution requirement for recipients, in recognition, in part, of the fact that this value-based safe harbor does not require parties to assume financial risk or meet certain traditional safeguards, such as a fair market value requirement. The care coordination arrangements safe harbor does not protect monetary payments, including payments for services such as radiology or imaging. Nothing in the risk-based safe harbors prevents parties from negotiating fair market value arrangements for services or from using the personal services and management contracts and outcomes-based payments safe harbor at paragraph 1001.952(d), which includes fair market value requirements.

While existing safe harbors could protect many care coordination arrangements, comments we received in response to the OIG RFI reflected that existing safe harbors are insufficient to protect the range of care coordination arrangements envisioned by the Regulatory Sprint. For example, apart from employment, there is no existing safe harbor protection for the sharing of personnel or infrastructure at below-market-value rates. Thus, the value-based safe harbors will provide protection to a broader range of care coordination arrangements than is presently available under existing safe harbors. With respect to the commenter that suggested evaluation was warranted prior to implementing the value-based safe harbors, we solicited feedback on the anticipated approach for rulemaking

in the RFI and solicited comments on specific safe harbors, an exception, and relevant considerations in the OIG Proposed Rule. We do not believe further evaluation is needed to inform the issuance of this final rule; indeed, further formal evaluation could delay regulatory flexibilities designed to facilitate innovative value-based care and care coordination arrangements.

With respect to concerns regarding industry consolidation, it is not the intent of this final rule to foster industry consolidation. The rule aims to increase options for parties to create a range of care coordination and value-based arrangements eligible for safe harbor protection, whether through employment, ownership, or contracts among otherwise unaffiliated, independent entities that wish to coordinate care. As explained elsewhere, the definition of a ''value-based enterprise'' is flexible, allowing for a broad range of participation and business structures. In addition, ''value-based arrangements'' are defined such that they can be among many participants or as few as two. The safe harbors are available to large and small systems and to rural and urban providers. We intend for this flexibility to ensure that smaller providers still have the opportunity to develop and enter into care coordination arrangements.

Comment: Several commenters highlighted the potential harms the proposed value-based safe harbors could pose to patients, *e.g.,* cherry-picking, provision of medically unnecessary care, or stinting on care. Commenters also expressed concern that the safe harbors could negatively impact patient freedom of choice or impinge on the patient-physician relationship. To address these concerns, commenters had varying suggestions. For example, some commenters urged OIG to insert patient transparency requirements in the value-based safe harbor that would mirror similar requirements in the Medicare Shared Savings Program. One such commenter stated transparency is necessary to ensure public confidence that the benefits of a value-based arrangement would not be exclusive to those party to the agreement.

Response: We share the commenters' interests in protecting patients against cherry-picking, the provision of medically unnecessary care, stinting on care, patient steering, and any inappropriate infringement on the patient-doctor relationship. Accordingly, we have finalized safeguards in each of the three value-based safe harbors related to these issues. We did not propose patient transparency or notice requirements in the OIG Proposed Rule for the value-based safe harbors because we believed it potentially would impose undue administrative burden on providers, and we are not including any such condition in this final rule.

Comment: We received a number of comments stating that our approach to the value-based safe harbors was not bold enough and would act as a barrier to advancing the coordination and management of care. For example, a commenter stated that the proposals, as drafted, would not advance care coordination and better quality outcomes because the OIG sets too many limits and boundaries within the value-based safe harbors. In addition, several commenters asserted that our definitions of certain key terms, such as value-based enterprise and VBE participant, were overly prescriptive. Other commenters asserted that our view of financial risk was too narrow and failed to recognize, among other things, that providers are already at substantial financial risk under existing financial incentives and penalties created by payment structures.

Response: We disagree with those commenters who stated that our definitions are too narrow or prescriptive and that the proposed value-based safe harbors are not bold enough because they would impose limits on the types of arrangements that are protected.

As discussed in section III.B.2, we have defined the value-based terminology to allow for a wide range of individuals and entities to participate in value-based arrangements. The value-based safe harbors do not attempt to cover the entire universe of potentially beneficial arrangements, nor the entire universe of what may constitute risk. Indeed, we acknowledged in the OIG Proposed Rule, and confirm here, that we understood that participants in value-based arrangements might assume certain types of risk other than downside financial risk for items and services furnished to a target patient population (*e.g.,* upside risk, clinical risk, operational risk, contractual risk, or investment risk).[12] We continue to believe our focus on downside financial risk is warranted because the assumption of downside financial risk incentivizes those making the referral and ordering decisions to control costs and deliver efficient care in a way the other types of risk may not.

Further, the care coordination arrangements safe harbor requires no assumption of downside risk by parties to a value-based arrangement. Accordingly, parties that do not meet the definition of taking on ''substantial downside financial risk'' or ''full financial risk'' may seek protection for certain value-based arrangements under the care coordination arrangements safe harbor. They may also look to the new safe harbor protection for outcomes-based payments at paragraph 1001.952(d)(2).

We have included parameters in the value-based safe harbors to protect against risks of fraud and abuse, such as overutilization, inappropriate patient steering, or stinting on care. Nothing in the rulemaking changes the premise of safe harbors themselves: They offer protection to certain arrangements that meet safe harbor conditions, but they do not purport to define all lawful arrangements. Parties with arrangements that do not fit in a value-based safe harbor may look to other safe harbors or the language of the statute itself. Parties also may request an advisory opinion from OIG to determine whether an arrangement meets the conditions of a safe harbor or is otherwise sufficiently low risk under the Federal anti-kickback statute to receive prospective immunity from administrative sanctions by OIG.

Comment: Multiple commenters recommended that, in lieu of a tiered approach to the value-based framework (*i.e.,* three value-based safe harbors, based upon the level of risk assumed by parties), OIG should create a single value-based arrangements safe harbor. The commenters asserted that such an approach would reduce the complexity of the value-based safe harbors.

Response: We appreciate the commenters' suggestion regarding ways to reduce complexity; however, we disagree with the commenters' recommendations to develop a single value-based arrangements safe harbor. The tiered approach we are finalizing in this rule supports the policy goals of the Regulatory Sprint regarding the transformation to value and offers parties flexibility to undertake arrangements that suit their needs. We do not believe that a one-size-fits-all approach would be feasible or effective to promote the transformation to value because we recognize there are many dimensions of value in health care that may look different for various stakeholders. To support the transformation to value, reflect that program integrity vulnerabilities change as parties assume more risk, and prevent unscrupulous behavior, we have adopted a tiered approach where the safeguards included in each of the value-based safe harbors are tailored according to, among other things, the

[12] 84 FR 55699 (Oct. 17, 2019).

degree of downside financial risk assumed by the parties.

Comment: In response to our solicitation of comments on whether to define the term ''value,'' we received varying comments. Some commenters supported our proposal to use the term in a non-technical way, with one asserting the term ''value'' is not a one-size-fits-all term of art. Others suggested that we reference—in the final definitions or otherwise—financial arrangements under advanced alternative payment models (APMs) to make clear that value-based arrangements in CMS-sponsored programs would receive protection under the value-based safe harbors.

Response: We agree with those commenters that noted that ''value'' is not a one-size-fits all term. We decline to use or define the term ''value'' for the purposes of these safe harbors because we believe industry stakeholders and those participating in value-based arrangements potentially protected by these safe harbors are best-positioned to determine value. Notably, however, we define other terms critical to the value-based safe harbors, including ''value-based purpose,'' ''value-based activity,'' and ''value-based arrangement.'' These defined terms adequately capture the concept of value without prescriptively defining ''value,'' which could inhibit flexibility and innovation. We also are not adopting the commenters' suggestion to define any term by referencing financial arrangements under advanced APMs. Financial arrangements under CMS-sponsored APMs may satisfy the definition of ''value-based arrangement'' and may serve as one of many sources for considering value in the delivery of care. In addition, organizations already participating in CMS-sponsored models may wish to look to the new safe harbor for those models at paragraph 1001.952(ii).

Comment: Several commenters requested that we offer additional clarity on key terms and concepts used throughout the value-based framework. For example, some commenters encouraged OIG to issue sub-regulatory guidance with respect to the value-based safe harbors, while others requested specific examples of the types of value-based arrangements that could be protected. Another commenter suggested that, in order to avoid confusion, OIG more closely align its value-based safe harbors with the requirements in the Medicare Shared Savings Program fraud and abuse waivers (*e.g.,* governing body approval of protected arrangements). Collectively, these commenters expressed concern that without further guidance from OIG, individuals and entities would remain too risk-averse to leverage the new safe harbors for value-based arrangements or would incur significant time and expense in creating a value-based enterprise that might not meet the required standards.

Response: Based on these comments, throughout this final rule, we have endeavored to provide additional clarity and examples of key terms and concepts. Parties also may use OIG's advisory opinion process to obtain a legal opinion on the application of OIG's fraud and abuse authorities to a particular arrangement. Regarding the request for greater alignment with the Medicare Shared Savings Program, we note that we drew from our experience with the waivers issued for the Medicare Shared Savings Program in drafting the value-based safe harbors, but we do not believe alignment with the waiver conditions would be appropriate for a number of reasons. First, CMS provides programmatic oversight of the Medicare Shared Savings Program that it would not provide to all value-based enterprises under this final rule. In addition, the waivers apply to certain remuneration related to one type of alternative payment model, whereas the safe harbors finalized in this final rule apply to a broader range of arrangements focused on value-based care. Finally, as discussed in more detail below, all individuals and entities can be VBE participants, whereas participation in the Medicare Shared Savings Program is more limited. Parties participating in CMS-sponsored models may wish to look at the new safe harbor for those models at paragraph 1001.952(ii), which is closely aligned with model requirements and takes into account CMS's oversight of those models and the Medicare Shared Savings Program.

Comment: Multiple commenters requested that OIG speak to the intersection of the proposed value-based safe-harbors with existing: (i) Financial arrangements that may not meet the four corners of the value-based safe harbors, despite otherwise being similar in concept; (ii) safe harbors; and (iii) state law and corporate practice of medicine requirements.

Response: By promulgating value-based safe harbors, we are not opining, directly or indirectly, on the legality of existing financial arrangements that may be similar in concept to value-based arrangements that may be protected under the new value-based safe harbors. Arrangements that do not meet all conditions of an applicable safe harbor are not protected by that safe harbor. Whether such an arrangement violates the Federal anti-kickback statute is a fact-specific inquiry. In addition, and as stated in the OIG Proposed Rule, parties to value-based arrangements may choose whether to protect such arrangements under existing safe harbors or under the new value-based safe harbors finalized in this final rule.

We have attempted to create significant flexibility under the Federal anti-kickback statute while recognizing that parties still must comply with applicable State laws. Nothing in these safe harbors preempts any applicable State law (unless such State law incorporates the Federal law by reference).

Comment: We received several comments that touched upon the applicability of the value-based safe harbors to commercial arrangements. For example, at least two commenters expressed support for extending the value-based safe harbor protections to participants in arrangements involving only commercial payor patients. Another commenter strongly recommended that OIG clarify in the final rule that the Federal anti-kickback statute is not implicated if a financial arrangement is strictly limited to commercial payor patients.

Response: Generally speaking, the Federal anti-kickback statute is not implicated for financial arrangements limited solely to patients who are not Federal health care program beneficiaries. However, to the extent the offer of remuneration pursuant to an arrangement involving only non-Federal health care program beneficiaries is intended to pull through referrals of Federal health care program beneficiaries or business, the Federal anti-kickback statute would be implicated and potentially violated. While nothing in the value-based safe harbors precludes financial arrangements limited solely to patients who are not Federal health care program beneficiaries, the parties would need to meet all requirements of the applicable value-based safe harbor, and a pull-through arrangement would not meet the requirement, in each value-based safe harbor found at (ee), (ff), and (gg), that the offeror of remuneration does not take into account the volume or value of, or condition the remuneration of referrals of, patients who are not part of the target patient population, or business not covered under the value-based arrangement.

Comment: A commenter recommended that OIG apply the value-based safe harbors retrospectively.

Response: As stated in the OIG Proposed Rule, the value-based safe

harbors will be prospective only and will be effective as of 60 days from the date this rule is published in the **Federal Register**. It is neither feasible nor desirable to confer safe harbor protection retrospectively under a criminal statute. Conduct is evaluated under the statute and regulations in place at the time of the conduct.

Comment: A commenter supported OIG addressing value-based contracting and outcomes-based contracting for the purchase of pharmaceutical products in future rulemaking, including rules around medication adherence. Another commenter urged OIG to promulgate a safe harbor in this final rule specific to value-based arrangements with manufacturers for the purchase of pharmaceutical products (as well as medical devices and related services).

Response: We did not propose, and thus are not finalizing, a safe harbor specifically for value-based arrangements with manufacturers for the purchase of their products. We may consider this topic, along with value-based contracting and outcomes-based contracting, for future rulemaking.

Comment: Separate and apart from outcomes-based contracting, a handful of commenters requested that we create new safe harbors or issue certain guidance. For example, a hospital association urged us to create a safe harbor to facilitate non-CMS advanced payment models. Another commenter suggested we issue guidance affording parties additional regulatory flexibility to the extent their financial arrangements are consistent with the goals of the value-based safe harbors but do not otherwise satisfy all conditions.

Response: We did not propose and are not finalizing a safe harbor specific to non-CMS advanced payment models. However, we refer the commenter to our substantial downside financial risk safe harbor at paragraph 1001.952(ff), as remuneration exchanged by the parties to the advanced payment model arrangement may be eligible for protection under that safe harbor.

We likewise are not issuing guidance to provide parties with additional regulatory flexibility to protect financial arrangements that are consistent with the goals of, but do not meet the requirements of, a value-based safe harbor. An arrangement must meet all conditions of the applicable value-based safe harbor for remuneration exchanged pursuant to the arrangement to receive protection.

Comment: A commenter asserted that the value-based safe harbors do not satisfy the requirements set forth in section 1128D of the Act for the promulgation of new safe harbors. Specifically, the commenter asserted that the value-based safe harbors do not specify payment practices that are protected under the Federal anti-kickback statute, as required by section 1128D, because they only outline a set of general principles.

Response: We disagree with the commenter. Section 1128D of the Act requires the Secretary to publish a notice soliciting proposals for, among other things, additional safe harbors specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) and shall not serve as the basis for an exclusion under section 1128(b)(7) and to publish proposed additional safe harbors, if appropriate, after considering such proposals. Consistent with that authority, the value-based safe harbors specify payment practices that will be protected if they meet a series of specific, enumerated requirements. Although a value-based safe harbor may protect remuneration exchanged pursuant to a diverse universe of value-based arrangements, all value-based arrangements within that universe share the features required by the applicable safe harbor.

For example, the payment practice specified in the care coordination arrangements safe harbor is the exchange of in-kind remuneration pursuant to value-based arrangement, where, among several other requirements, the parties establish legitimate outcome measures to advance the coordination and management of care for the target patient population; the arrangement is commercially reasonable; and the recipient contributes at least 15 percent of either the offeror's cost or the fair market value of the remuneration. If an arrangement fails to meet any one of the safe harbor's requirements, it cannot receive protection under the safe harbor. This approach is consistent with the approach taken in other safe harbors that are not specific as to the type of arrangement. For example, the personal services and management contracts safe harbor protects any payments from a principal to an agent, as long as a series of standards are met.

Comment: Numerous commenters requested that OIG and CMS seek greater alignment across their respective value-based rules. According to some of these commenters, further alignment would reduce administrative burden, confusion, and regulatory uncertainty. Commenters were generally in favor of OIG revising its proposed value-based safe harbors to more closely parallel CMS's proposed value-based exceptions to the physician self-referral law. Commenters suggested that CMS's proposed value-based exceptions would protect a broader universe of beneficial innovative arrangements, without greater fraud and abuse risk. Accordingly, commenters urged OIG to create a safe harbor for any value-based arrangement that otherwise met a physician self-referral law exception or, alternatively, state that compliance with the physician self-referral law would rebut any implication of intent under the Federal anti-kickback statute. Commenters also advocated that OIG adopt certain CMS proposed definitions, *e.g.,* CMS's ''volume or value'' definition.

Response: As explained in more detail in section III.A.1 of this preamble, we are mindful of reducing burden on providers and other industry stakeholders, and we have sought to align value-based terminology and safe harbor conditions with those being adopted by CMS as part of the Regulatory Sprint wherever possible. However, complete alignment is not feasible because of fundamental differences in statutory structures and penalties across the two laws, as well as differences in how anti-kickback statute safe harbors and physician self-referral law exceptions operate. For example, the physician self-referral law applies to referrals by physicians for specified designated health services, whereas the anti-kickback statute applies to referrals by anyone of any Federal health care program business. Fitting in an exception to the physician self-referral law is mandatory, whereas using safe harbors is voluntary. In designing our safe harbors, we have included conditions designed to ensure that protected arrangements are not disguised kickback schemes, and we recognize that, for purposes of those arrangements that implicate both the physician self-referral law and the Federal anti-kickback statute, the value-based safe harbors may therefore protect a narrower universe of arrangements than CMS's exceptions.

We do not agree as a matter of law that compliance with the physician self-referral law would rebut any implication of intent under the Federal anti-kickback statute. We did not propose to, and do not, adopt CMS's proposed interpretation of the term ''takes into account the volume or value of referrals or other business generated.'' We have aligned terminology used in the value-based framework and set forth at paragraph 1001.952(ee) in our rule, as described below.

2. Value-Based Terminology (42 CFR 1001.952(ee))

We proposed to define at paragraph 1001.952(ee)(12) the following terms: ''value-based enterprise'' (''VBE''), ''value-based arrangement,'' ''target patient population,'' ''value-based activity,'' ''VBE participant,'' ''value-based purpose,'' and ''coordination and management of patient care.'' We summarize the proposal for each of these definitions and the final rule in turn below. These definitions are now located at paragraph 1001.952(ee)(14) of the final rule and cross-referenced in the safe harbors at paragraphs 1001.952(ff), (gg), and (hh). In this final rule, we have added definitions at paragraph 1001.952(ee)(14) for the following terms that are used in connection with determining eligibility of certain types of entities to use the safe harbors at paragraphs 1001.952(d)(2), (ee), (ff), (gg), and (hh): ''limited technology participant,'' ''digital health technology,'' and ''manufacturer of a device or medical supply.'' These definitions are discussed in section III.B.2.e.

a. Value-Based Enterprise (VBE)

Summary of OIG Proposed Rule: We proposed to define the term ''value-based enterprise'' or ''VBE'' as two or more VBE participants: (i) Collaborating to achieve at least one value-based purpose; (ii) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (iii) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (iv) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Summary of Final Rule: We are finalizing, with modification, the definition of ''value-based enterprise.''

i. General

Comment: Multiple commenters supported the definition of ''value-based enterprise,'' as proposed, and the flexibility the definition offers. A commenter appeared to ask OIG to revise the definitions of ''value-based enterprise,'' ''value-based arrangement,'' and ''value-based activity'' so that they do not incorporate and rely on other defined terms. Another commenter suggested a broader definition of ''VBE'' that would allow affiliates of a VBE to participate within the VBE without becoming VBE participants.

Response: The definition of ''value-based enterprise'' is intended to be broad and flexible to encompass a wide range of VBEs, from smaller VBEs comprised of only two or three parties to large VBEs, such as entities that function similar to ACOs. We decline to expand the definition further to allow affiliates of VBE participants to participate in a VBE without becoming VBE participants. We designed the value-based framework, including the requirement for parties to be either a VBE or a VBE participant, to ensure the remuneration that the safe harbors protect is exchanged pursuant to a value-based arrangement where all parties are striving to achieve value-based purposes. VBE participants can continue to enter into arrangements with affiliates and other non-VBE participants and may look to other available safe harbors for potential protection for those arrangements.

We also decline to revise the definitions of ''value-based enterprise,'' ''value-based arrangement,'' and ''value-based activity'' to omit references to other defined terms. The value-based terminology we are finalizing works in concert to explain the universe of value-based arrangements under which the exchange of remuneration may receive safe harbor protection. For example, because the terms ''VBE participant,'' ''value-based purpose,'' and ''value-based arrangement'' are fundamental to the definition of ''value-based enterprise,'' we are finalizing a definition of ''value-based enterprise'' that references those terms.

Comment: A commenter asked whether parties could prove collaboration to achieve one or more value-based purposes by measuring the amount of time a VBE participant has been taking part in a value-based activity.

Response: To accommodate a broad range of VBEs, from small to large, this final rule does not prescribe how VBE participants prove that they are collaborating to achieve at least one value-based purpose, as required by the definition of ''value-based enterprise''; it is incumbent on the VBE participants to demonstrate that they are meeting this requirement. For example, time spent on value-based activities, records of collaboration between parties, and participation in applicable meetings, could all be relevant factors, depending on the unique nature and circumstance of the VBE and the arrangements among the VBE participants.

Comment: A commenter expressed concern that the costs of forming a VBE could be prohibitive for small and rural providers and providers serving underserved populations, and it appeared to ask OIG to create an online portal that parties could use to create VBEs. Another commenter asked OIG to state expressly that a VBE may add individual physicians and other clinicians as VBE participants on an ongoing basis and still meet the definition of ''VBE.''

Response: The definition of ''VBE'' is intended to be both broad and flexible to accommodate providers, suppliers, and other entities of varying sizes and financial means seeking to participate in value-based arrangements. The definition, as finalized, will allow small and rural providers and providers serving underserved populations to form VBEs that correspond in scope and design with the VBE participants' resources. For example, we anticipate that parties could form a VBE with a single value-based arrangement, and a VBE could be comprised of only two VBE participants. We did not propose to create an online portal for the creation of VBEs, and we are therefore not establishing an online portal in this final rule. We also confirm that VBE participants may join and leave a VBE throughout the existence of the VBE, but we note that a VBE always must have two or more VBE participants to meet the definition of ''value-based enterprise.''

Comment: A commenter recommended that we require a value-based enterprise to utilize electronic health records so that each entity participating in the value-based enterprise has a strong data platform to track and evaluate the VBE's inputs and outcomes. According to the commenter, data from the EHR systems is critical to care delivery and care coordination.

Response: We agree that EHR systems can help individuals and entities within the VBE facilitate the coordination and management of care but did not propose to require, and thus are not requiring, VBEs or VBE participants to use them. Moreover, we intend for entities of varying sizes and with different levels of funding and access to technology to be able to utilize the value-based safe harbors. While we continue to support the Department's goal of continued adoption and use of interoperable EHR technology that benefits patient care, we are concerned that requiring utilization of EHR may unduly limit the ability of some entities to form a VBE. Donations of EHR by VBEs to VBE participants can be protected by the value-based safe harbors if all conditions are met. Alternatively, VBE and VBE participants may use the EHR safe harbor that this final rule makes permanent.

Comment: Commenters asked how the definition of ''value-based enterprise'' would apply to integrated delivery systems, with a commenter specifically inquiring as to how entities within a

larger integrated delivery system that enter into arrangements with a payor for shared savings and losses could subsequently share such savings or losses with downstream contracted or employed physicians. The commenter asked whether each party offering or receiving remuneration would be required to be a party to an agreement with the payor or if separate agreements between the downstream entities would suffice. Another commenter asked OIG to confirm whether an already existing integrated delivery system, ACO, or similar entity could meet the requirements of a VBE or whether that entity must establish a new value-based enterprise to use the value-based safe harbors. A commenter asserted that the value-based definitions and safe harbors should include integrated delivery systems, accountable care, team-based care, coordinated care (including for dual eligible beneficiaries), bundled payments, payments linked to quality or outcomes, Medicaid waiver programs, and Medicare managed care, value-based, or delivery system reform directed payments. A commenter recommended that the final rule deem an existing ACO to be compliant with the requirements of an applicable safe harbor to help retain ACOs as a central organizational structure, reduce regulatory burden, reduce risk of whistleblower or regulatory challenges, and minimize the need for creation of arrangements outside the ACOs. For each value-based safe harbor the commenter made specific suggestions: That OIG deem ACO outcome measures to meet the outcome measures requirement for care coordination arrangements; and for the substantial downside financial risk and full financial risk safe harbors, that all safe harbor conditions would be deemed met if the requisite level of downside financial risk were present.

Response: The final rule, including the value-based terminology, value-based safe harbors, and other safe harbors we are finalizing, offers several potential pathways for protection for the types of arrangements noted by the commenters, provided all applicable definitions and safe harbor conditions are satisfied. An existing integrated delivery system, ACO, or comparable entity could potentially qualify as a ''value-based enterprise'' and meet all of the requirements of the definition to use the value-based safe harbors we are finalizing. Arrangements for shared savings or losses and certain bundled payments could be protected under the substantial downside and full financial risk safe harbors, which protect in-kind and monetary remuneration exchanged between a VBE and a VBE participant. Under these safe harbors, a hospital that is a VBE participant could enter into a value-based arrangement with a VBE, pursuant to which the VBE shares savings or losses with the hospital VBE participant. However, this arrangement could not be protected under the care coordination arrangements safe harbor, which does not protect the exchange of monetary remuneration. Monetary remuneration, including payments linked to outcomes, could qualify for protection under the safe harbor for personal services and management contracts and outcomes-based payments at paragraph 1001.952(d)(2). Neither the substantial downside financial risk safe harbor nor the full financial risk safe harbor protects the exchange of remuneration between entities downstream of the VBE (*i.e.,* between VBE participants, a VBE participant and a downstream contractor, or downstream contractors). Apart from the value-based safe harbors, some managed care arrangements could be structured to fit in the existing managed care safe harbors at paragraphs 1001.952(t) and 1001.952(u). ACOs and others in CMS-sponsored models could use the new safe harbor at paragraph 1001.952(ii).

We did not propose and are not adopting a deeming provision for ACOs, as recommended by the commenter. Under the final value-based safe harbors, ACOs would need to meet all applicable safe harbor conditions. We have designed the value-based terminology and safe harbors to be flexible to accommodate a range of VBE types, structures, and arrangements, including ACOs. Moreover, when participating in a CMS-sponsored model, an ACO might rely on an existing fraud and abuse waiver or the new safe harbor for CMS-sponsored models at paragraph 1001.952(ii), rather than a value-based safe harbor.

To the commenter's question regarding separate agreements, although the substantial downside financial risk and full financial risk safe harbors would not protect any shared savings or losses (or other remuneration) between the hospital VBE participant and its downstream employed or contracted physicians, the VBE could enter into value-based arrangements directly with physicians who are VBE participants in order to share savings or losses with the physicians. We note, however, that, consistent with all other safe harbors, compliance with the value-based safe harbors is not compulsory. Parties may enter into lawful arrangements for value-based care that do not meet a safe harbor. Other safe harbors may be relevant to protect remuneration exchanged in a value-based arrangement, such as the personal services and management contracts safe harbor or a managed care safe harbor, depending on the circumstances. The OIG advisory opinion process also remains available.

Comment: A commenter asked whether VBEs must undergo a formal process to receive protection under the new safe harbors.

Response: All safe harbors to the Federal anti-kickback statute, including the new safe harbors we are finalizing in this final rule, are voluntary, and parties do not need to undergo any process or receive any affirmation from the Federal Government in order to receive protection. We note that qualifying as a value-based enterprise is not sufficient to obtain protection under the value-based safe harbors. To be protected, the remuneration exchanged between or among parties to the VBE must squarely meet all conditions of an available safe harbor. Parties that wish for OIG to opine on whether an arrangement satisfies the criteria of a safe harbor may submit an advisory opinion request.

Comment: A commenter stated that an entity that qualifies as a VBE should be deemed to meet the Federal Trade Commission (FTC) and Department of Justice (DOJ) requirements for clinical integration.

Response: Whether a value-based enterprise meets the FTC and DOJ requirements for clinical integration is outside the scope of this rulemaking and thus the issue raised by the commenter is not addressed in this rule.

Comment: Several commenters asked OIG to include references to free clinics, charitable clinics, and charitable pharmacies in the definition of ''value-based enterprise,'' stating that hospitals otherwise will remain risk averse to establishing or continuing partnerships with such entities. Another commenter asked OIG to confirm that the terms ''value-based enterprise,'' ''value-based arrangement,'' and ''value-based activity'' apply exclusively to the new safe harbors and not in other contexts, such as state Medicaid programs, to ensure the new value-based terminology does not disrupt the administration of existing value-based arrangements.

Response: We do not believe it is necessary to include references to any specific entities in the definition of ''value-based enterprise.'' While the commenter requested that we reference these entities in the definition of ''VBE,'' we note that under this final rule all individuals and entities are eligible to

be VBE participants (other than a patient acting in their capacity as a patient). The definitions we are finalizing for the value-based terminology, including the terms ''value-based enterprise,'' ''value-based arrangement,'' and ''value-based activity,'' do not apply outside of the safe harbors being finalized in this rule. Given OIG's limited authority in the context of this rulemaking, we do not purport to define these terms for other purposes, including for State Medicaid programs; however, the safe harbors could protect remuneration resulting from value-based arrangements involving Medicaid beneficiaries (to the extent that all applicable safe harbor conditions are satisfied). CMS is using the same terminology for its new value-based exceptions under the physician self-referral law.

Comment: A commenter asserted that the proposed definitions of ''value-based enterprise,'' ''value-based arrangement,'' ''value-based activity,'' and ''VBE participant'' apply only to the care coordination arrangements safe harbor and not to the substantial downside financial risk safe harbor or the full financial risk safe harbor.

Response: The commenter's apparent confusion arises from the language in proposed paragraph 1001.952(ee) that states, ''[f]or purposes of this paragraph (ee), the following definitions apply.'' Notwithstanding this language, the substantial downside financial risk safe harbor and the full financial risk safe harbor expressly incorporate the definitions of ''value-based enterprise,'' ''value-based arrangement,'' ''value-based activity,'' and ''VBE participant'' set forth in paragraph 1001.952(ee).

Comment: While supporting the proposed definition of ''value-based enterprise,'' several commenters requested that OIG and CMS align any modifications to the final definition of ''VBE.'' According to the commenter, identical definitions would allow stakeholders to place more focus on the delivery of value-based care because they would not need to navigate different legal frameworks under the Federal anti-kickback statute and the physician self-referral law.

Response: We are finalizing a definition of ''value-based enterprise'' that remains aligned with the definition finalized by CMS.

Comment: Some commenters asserted that Indian health programs should be deemed to meet the definition of ''value-based enterprise'' even if they do not meet each requirement of the definition because Tribes, as sovereign governments, do not enter into agreements in which another entity has governing authority or control over any part of the Tribe. In addition, they explained that Indian health programs have several features of the proposed definition (*e.g.,* Indian health programs are held accountable by the governing body of the Tribe or the United States Congress, in the case of IHS-run programs). Such commenters asserted that requiring Indian health programs to meet any additional requirements would exclude or unnecessarily burden those programs.

Similarly, several commenters requested that OIG address whether Indian health programs could be a VBE participant and recommended that the definition expressly state that Indian health programs may be VBE participants. Another commenter expressed concern that Indian health programs may not meet the proposed definition of VBE participant because Tribes are sovereign nations that will not enter into agreements with another entity with authority over the Tribe.

Response: Indian health programs, as well as other individuals and entities, may themselves constitute VBEs or may form VBEs if they meet all requirements in the definition of such term. We are not promulgating any exceptions to the requirement that parties form a VBE in order to use one of the value-based safe harbors or the patient engagement and support safe harbor because we believe the definition of ''value-based enterprise'' is sufficiently broad and flexible to allow Indian health programs to qualify as or form VBEs.

In addition, under our revised definition of a ''VBE participant,'' all types of entities can be VBE participants, including Indian health programs and Indian health care providers that engage in at least one value-based activity as part of a VBE.

ii. Accountable Body

Comment: Multiple commenters supported the proposed requirement that a VBE have an accountable body that is responsible for financial and operational oversight of the VBE, while some expressed concerns regarding the requirement. For example, some commenters asserted that parties would incur significant legal expenses to create an accountable body, which could discourage participation in VBEs, and questioned whether small or rural practices have the resources necessary to implement an accountable body. A commenter suggested OIG exempt smaller VBEs from the requirement to have an accountable body, particularly where the VBE is comprised only of individuals or small physician practices. Another noted that the requirement to have an accountable body could create tension between VBE participants when determining who will assume such role.

Response: We do not believe the requirement for a VBE to have an accountable body or responsible person places an undue financial or administrative burden on VBEs or VBE participants, particularly because the definition of ''value-based enterprise'' affords parties the flexibility to create VBEs and accountable bodies that range in scope and complexity. We are not exempting small or other VBEs from the requirement to have an accountable body or responsible person. We do not expect that small VBEs would have the same resources as larger VBEs for this function or would structure the function in the same way. A VBE should have an accountable body or responsible person that is appropriate for its size and resource and is capable of carrying out the associated responsibilities. Any potential for conflict among VBE participants is a matter for the parties to address in their private contractual or other arrangements and does not warrant an exception to the accountable body requirement, which serves an important oversight and accountability function in the VBE.

Comment: Commenters generally supported the flexibility for parties to tailor the accountable body to the complexity and sophistication of the VBE. Multiple commenters requested additional clarification on the nature and composition of the accountable body, including how and by whom the accountable body would be organized and whether the accountable body must be comprised of at least one representative from each VBE participant.

A commenter asked OIG to clarify whether ACOs that already have governing bodies in place need to establish an additional accountable body or responsible person to meet the definition of ''VBE.'' Another commenter asked whether the safe harbor conditions applicable to accountable bodies are at least as rigorous as the conditions applicable to governing bodies in the fraud and abuse waivers issued for purposes of the Medicare Shared Savings Program.

Response: We are not prescribing how VBE participants or VBEs form or otherwise designate an accountable body or responsible person in order to give parties flexibility to do so in a manner conducive to the scope and objectives of the VBE and its resources. For instance, a representative from each VBE participant in a VBE could, but is not required to, be part of the VBE's

accountable body. Where parties already have a governing body that constitutes an accountable body or responsible person, such parties are not required to form a new accountable body or designate a responsible person for purposes of creating a VBE. While the requirements for the accountable body or responsible person are not as stringent as the requirements for an ACO's governing body in the fraud and abuse waivers issued for purposes of the Medicare Shared Savings Program, we have concluded that the safe harbor requirements for the accountable body strike the right balance between allowing for needed flexibility for parties wanting to form and operate VBEs and providing for appropriate VBE oversight and accountability.

Comment: Multiple commenters supported a range of additional requirements for VBE participants related to the accountable body, including requirements to: (i) Recognize the oversight role of the accountable body affirmatively; (ii) agree in writing to cooperate with the accountable body's oversight efforts; and (iii) report data to the accountable body to enable it to access and verify VBE participant data related to performance under value-based arrangements. Another commenter opposed additional requirements on VBE participants, stating that they would be unnecessary formalities that would constrain use of the value-based safe harbors for existing arrangements that might otherwise meet a value-based safe harbor's terms. Other commenters also asked what, if any, oversight OIG would expect from VBE participants, themselves, in addition to the oversight conducted by the accountable body.

Response: It is important for the parties to a value-based arrangement to support and cooperate with the accountable body or responsible person. However, we are not finalizing requirements for VBE participants to recognize affirmatively the oversight role of the accountable body, agree in writing to cooperate with its oversight efforts, or report data. On balance, such requirements would introduce a level of unnecessary administrative detail and impose unnecessary administrative burden on many VBEs, particularly small or rural entities. Parties can themselves establish mechanisms to ensure the ability of the accountable body or responsible person to fulfill its obligations through, by way of example only, a term in arrangements between the VBE and its VBE participants that requires VBE participants to cooperate with the accountable body or responsible person's oversight efforts.

Whether VBE participants must conduct additional oversight depends on the applicable safe harbor. Parties relying on safe harbor protection may want to ensure all applicable safe harbor requirements, including those related to oversight, are met because failure to satisfy these requirements would result in the loss of safe harbor protection for the remuneration at issue. Notwithstanding this fact, where a VBE participant or VBE has done everything that it reasonably could to comply with the safe harbor requirements applicable to that party but the remuneration exchanged loses safe harbor protection as a result of another party's noncompliance, the compliant party's efforts to take all reasonable steps would be relevant in a determination of whether such party had the requisite intent to violate the Federal anti-kickback statute.

Comment: We received support for, and opposition to, a requirement for the accountable body to have more specific responsibilities for overseeing certain aspects of the VBE, including utilization of items and services; cost; quality of care; patient experience; adoption of technology; and quality, integrity, privacy, and accuracy of data related to each value-based arrangement. However, several commenters cautioned against overly prescriptive oversight obligations, with many commenters noting that the appropriate scope, methodology, and risk areas for monitoring and oversight will vary significantly based on the activities an entity is undertaking. According to several commenters, the program integrity benefits of any additional requirements on the accountable body would be outweighed by increased administrative burden.

Response: We are not requiring more specific oversight responsibilities for the accountable body. The type of data the accountable body should monitor and assess could vary by VBE and by value-based arrangement, and therefore we are not imposing more prescriptive requirements on the accountable body with respect to its oversight responsibilities. However, in the full financial risk safe harbor, we are finalizing a requirement that the VBE provide or arrange for a quality assurance program for services furnished to the target patient population that protects against underutilization and assesses the quality of care furnished to the target patient population.

Comment: Multiple commenters supported a requirement for VBEs to institute a compliance program to facilitate the accountable body's or responsible person's obligation to identify program integrity issues, with some also favoring requirements for periodic review of patient medical records to ensure compliance with clinical standards or for the designation of a compliance officer to oversee the VBE and its value-based arrangements. One commenter recommended that VBE participants agree to a code of ethics related to compliance oversight.

In contrast, multiple commenters opposed a requirement for the VBE to have a compliance program. Some asserted it would create an additional burden on VBEs without substantially reducing the risk of fraud and abuse. Commenters expressed concern that a compliance program requirement could result in inconsistent policies or duplicative administrative obligations if VBE participants already have compliance programs in place. Another commenter stated that such a requirement is unnecessary because VBEs are independently at risk for safe harbor compliance. A commenter recommended that, if OIG requires a VBE to have a compliance program, OIG should permit the VBE to meet such a requirement by: (i) Developing a compliance program specific to the VBE and its VBE participants, (ii) adopting an existing compliance program held by one of the VBE participants, or (iii) requiring an attestation from each VBE participant that it has a compliance program and conducts annual compliance reviews. Another commenter recommended that OIG provide model compliance provisions that could be included in agreements between parties in a VBE.

Response: For purposes of these safe harbors, we are not requiring the VBE or its accountable body or responsible person to have a compliance program or to review patient medical records periodically. We also are not requiring an attestation or other agreements from each VBE participant that it has a compliance program and conducts annual compliance reviews. Compliance programs are an important tool for, among other things, monitoring arrangements, identifying fraud and abuse risks, and, where necessary, implementing corrective action plans. While it is our view that robust compliance programs are a best practice for all VBEs and VBE participants, we are not including specific compliance program requirements or providing model compliance provisions because VBEs of varying sizes and scopes may have and need different types of compliance programs. We anticipate many VBE participants already have compliance programs and may want to

consider updating these programs to reflect any new arrangements entered into as part of the VBE.

A compliance program requirement for VBEs would necessitate that we articulate specific compliance program criteria, which we do not believe would be feasible or desirable, particularly in light of the expected variation of VBEs. We also are not requiring the VBE to designate an individual to serve as a compliance officer. For purposes of this rule, the accountable body or responsible person acts as an oversight body that performs a compliance function. In this respect, and as we stated in the OIG Proposed Rule, we believe the accountable body or responsible person would be well-positioned to identify program integrity issues and to initiate action to address them, as necessary and appropriate. VBEs may elect to have designated compliance officers if they so wish.

Comment: A commenter asked whether the accountable body and VBE participants should expect a higher degree of auditing and oversight from OIG than entities not involved in a value-based enterprise.

Response: OIG provides independent and objective oversight of the programs and operations of the Department. We anticipate that individuals and entities that are part of a value-based enterprise will be subject to OIG's program integrity and oversight activities to the same extent as other individuals and entities that receive Federal health care program funds or treat Federal health care program beneficiaries.

Comment: Some commenters supported a requirement for the accountable body or responsible person to have a duty of loyalty to the VBE, particularly for accountable bodies serving larger VBEs. The commenters asserted that a duty of loyalty would be appropriate given the lack of programmatic oversight as compared to CMS-sponsored models and would help reduce certain risks (*e.g.,* stinting on care or providing medically unnecessary care). Other commenters suggested that the accountable body should have a duty of loyalty to the patients within the VBE.

Multiple commenters opposed requiring the accountable body or responsible person to have a duty of loyalty to the VBE, stating that it would create conflicts of interest for accountable body members that are, or are employed by, a VBE participant. Some commenters asserted that a duty of loyalty would necessitate the use of a third-party entity to serve as the accountable body, which could be cost prohibitive for small and rural providers, while others noted that large VBE participants may be unwilling to cede oversight responsibilities to an independent third party. A commenter proposed an alternative requirement for the accountable body or responsible person to act in furtherance of the VBE's value-based purpose(s).

Response: We are not requiring the accountable body or responsible person to have a duty of loyalty to the VBE because we agree with commenters that a duty of loyalty often could create conflicts of interest for VBE participants and employees of VBE participants who otherwise would serve as members of the accountable body. We also agree that a duty of loyalty requirement could necessitate the use of independent third parties to serve as the accountable body, which could be cost prohibitive for smaller VBEs. While we are not implementing a requirement for the accountable body or responsible person to have a duty of loyalty or to act in furtherance of the VBE's value-based purpose(s), we believe the accountable body or responsible person necessarily must act in furtherance of the VBE's value-based purpose(s) to fulfill its oversight responsibilities. Parties are free to include this duty in their contractual arrangements.

Comment: A commenter asked OIG to require the accountable body to submit data to the Department to demonstrate continued compliance with the applicable safe harbor and progress in improving outcomes and reducing costs. A commenter also asserted that OIG should require the accountable body or responsible person to implement a process for patients to express concerns and for the VBE to resolve such concerns, and others recommended that OIG ensure that VBE participants secure informed consent for each patient treated within a VBE.

Response: We are not requiring accountable bodies or responsible persons to submit data to the Department for purposes of safe harbor compliance because we do not think the program integrity benefits of requiring data submission for safe harbor compliance would outweigh the administrative burden on both the government and the individuals and entities serving as accountable bodies or responsible persons. Notwithstanding the foregoing, we remind readers that OIG provides independent, objective oversight of HHS programs. Nothing in this rule changes OIG's authorities to request data for its oversight purposes. In addition, and as explained further below in section III.3.n.v, OIG will continue to evaluate whether to modify the care coordination arrangements safe harbor in the future to include a requirement that the VBE affirmatively submit certain data or information.

Due to administrative burden concerns, we are not requiring the accountable body or responsible person to implement a process for patients to express concerns or ensure that VBE participants secure informed consent for each patient treated within a VBE. Such requirements may be useful processes for VBEs to consider in ensuring safe harbor compliance.

iii. Governing Document

Comment: Commenters expressed general support for a governing document requirement. Some commenters asked whether the written document forming the value-based arrangement could also constitute the governing document, and another commenter questioned whether an existing payor contract could serve as a governing document. Another commenter requested that OIG permit a collection of documents to constitute a governing document.

Response: A single document could constitute both the VBE's governing document and the writing required for a value-based arrangement so long as it includes all of the requisite requirements for each writing. In addition, an existing payor contract could qualify as a governing document so long as it describes the value-based enterprise and how the VBE participants intend to achieve the VBE's value-based purpose(s). However, we decline to permit a governing document for a VBE to be set forth in multiple writings. We permit the writing requirement in each new value-based safe harbor to be satisfied by a collection of writings because each party to a value-based arrangement must sign the writing; in contrast, the governing document of the VBE does not require any signatures. Creation of one governing document, that may be amended over time as the value-based activities, VBE participants, or other features of the VBE evolve, will help ensure that there is a clearly identifiable governance structure for the VBE.

Comment: Some commenters expressed concern that the requirement for a VBE to have a governing document could be burdensome, particularly for small and rural practices and practices serving underserved areas. Another commenter requested a checklist or model terms for a governing document, and another commenter asked for clarification of requirements for the document.

Response: We appreciate commenters' concerns regarding the burden that

developing a governing document may place on certain individuals or entities. We are finalizing the proposed definition of ''value-based enterprise,'' which does not prescribe a specific format or content for the governing document, other than it must describe the VBE and how the VBE participants intend to achieve its value-based purpose(s). This definition is designed to be flexible so that small and rural practices and practices serving underserved areas wishing to establish VBEs can craft governing documents appropriate to their size and the nature of their VBE. We anticipate that VBEs of different sizes and purposes will have different types of governing documents with different terms. The core requirement is that the governing document must describe the value-based enterprise and how the VBE participants intend to achieve the VBE's value-based purpose(s), regardless of the format of the document. This definition offers parties significant flexibility to craft a value-based enterprise and a governing document commensurate with the scope and sophistication of the VBE.

As we stated in the preamble to the OIG Proposed Rule, the governing document requirement provides transparency regarding the structure of the VBE, the VBE's value-based purpose(s), and the VBE participants' roadmap for achieving the purpose(s). We do not believe a checklist for creating a governing document is necessary because the requirements for the governing document are set forth in the definition of ''value-based enterprise,'' itself. In addition, we decline to provide model terms because they could inhibit parties from developing terms that appropriately reflect the unique nature and circumstances of their value-based enterprises.

b. Value-Based Arrangement

Summary of OIG Proposed Rule: We proposed to define the term ''value-based arrangement'' to mean an arrangement for the provision of at least one value-based activity for a target patient population between or among: (i) The value-based enterprise and one or more of its VBE participants; or (ii) VBE participants in the same value-based enterprise. This proposed definition reflected our intent to ensure that each value-based arrangement is aligned with the VBE's value-based purpose(s) and is subject to its financial and operational oversight. It further reflected our intent for the value-based arrangement's value-based activities to be undertaken with respect to a target patient population.

We noted in the OIG Proposed Rule that we were considering whether to address a concern about potentially abusive practices that could be characterized as the coordination and management of care by precluding some or all protection under the proposed value-based safe harbors for arrangements between entities that have common ownership, either through refinements to the definition of ''value-based arrangement'' or by adding restrictions on common ownership to one or more of the proposed safe harbors at paragraphs 1001.952(ee), (ff), or (hh).

Summary of Final Rule: We are finalizing, with modification, the definition of ''value-based arrangement.'' We are modifying the regulatory text to clarify that only the value-based enterprise and one or more of its VBE participants, or VBE participants in the same value-based enterprise, may be parties to a value-based arrangement. We are not precluding protection for arrangements between entities that have common ownership in the definition of ''value-based arrangement,'' nor in the individual safe harbors.

Comment: Many commenters supported the proposed definition of ''value-based arrangement'' and, in particular, appreciated the flexibility afforded by the definition, which the commenters posited will allow parties to design a range of arrangements that may qualify for protection under the value-based safe harbors, including arrangements between two providers that include only a single value-based activity. Commenters also supported our proposal in the OIG Proposed Rule that the definition covers commercial and private insurer arrangements.

Response: We reiterate in this final rule that the definition of ''value-based arrangement'' is broad enough to capture commercial and private insurer arrangements. The definition is intended to afford parties significant flexibility. In addition, in response to comments, we are modifying the definition text to clarify our intent that ''value-based arrangement'' capture arrangements for care coordination and certain other value-based activities among VBE participants within the same VBE, as indicated in the OIG Proposed Rule,[13] by revising the definition so that the value-based arrangement may only be between: (i) The value-based enterprise and one or more of its VBE participants; or (ii) VBE participants in the same value-based enterprise.

We emphasize that qualification as a value-based arrangement is necessary, but not sufficient, to protect remuneration exchanged pursuant to that arrangement; all conditions of an applicable safe harbor must be met.

Comment: A commenter opposed the definition of ''value-based arrangement,'' expressing concern that it is too broad and vague and could be used as a mechanism to force the exclusive use of a particular product or particular provider. In addition, the commenter believed the definition could allow health care entities to engage in abusive practices by using a value-based safe harbor to funnel remuneration under the guise of a value-based arrangement.

Response: We have addressed the commenter's concern with respect to exclusive use through a condition in the care coordination arrangements safe harbor at paragraph 1001.952(ee). We acknowledge and agree with the commenter's concern that parties might engage in abusive practices under the guise of a value-based arrangement; to that end, we have included robust safeguards in each value-based safe harbor to mitigate these concerns.

Comment: A commenter requested clarification as to whether current arrangements would be affected and would need to be restructured to meet the definition of a ''value-based arrangement.''

Response: There is nothing in this final rule that requires parties to an existing arrangement to restructure that arrangement to meet the new definition of a ''value-based arrangement.'' Parties to an existing arrangement that wish to rely on the protection of one of the value-based safe harbors may want to review their arrangement to assess whether it fully meets the definition of a ''value-based arrangement'' and, thus, could be eligible for protection under a value-based safe harbor if all safe harbor conditions are met.

Comment: Several commenters requested clarification regarding the statement in the OIG Proposed Rule that the definition of ''value-based arrangement'' is intended to capture arrangements for care coordination and certain other value-based activities among VBE participants within the same VBE.[14] Specifically, commenters requested clarification regarding how this statement corresponds with the requirement in each proposed value-based safe harbor that the value-based arrangement have as a value-based

[13] 84 FR 55702 (Oct. 17, 2019).

[14] 84 FR 55702 (Oct. 17, 2019).

purpose the coordination and management of care.

Response: The definition of ''value-based arrangement'' and the requirements for protection under the value-based safe harbors are consistent when read together. The term ''value-based arrangement'' means an arrangement for the provision of at least one ''value-based activity'' for a target patient population. The definition does not specify which value-based purpose(s) the value-based activity (or activities) must be designed to achieve. In this respect, the definition of ''value-based arrangement'' is broader than the requirements of some of the value-based safe harbors.

Value-based arrangements are not *de facto* safe harbor protected. Rather, an arrangement that meets the definition of a ''value-based arrangement'' is eligible to seek protection in a value-based safe harbor. For safe harbor protection, it must squarely satisfy all safe harbor conditions. For reasons explained elsewhere in this preamble, the care coordination arrangements safe harbor requires a direct connection to the first value-based purpose, the coordination and management of patient care, which is a central focus of this rulemaking. The substantial downside financial risk arrangements safe harbor requires a direct connection to any one of the first three value-based purposes, and the full financial risk arrangements safe harbor requires a connection to any one of the four value-based purposes, in recognition of the parties' assumption of risk and the lower risk of traditional fee-for-service fraud. The substantial downside financial risk safe harbor and the full financial risk safe harbor, as finalized, do not require a direct connection to the coordination and management of care for the target patient population.

In addition, the definition of ''value-based arrangement'' is consistent with the definition used in CMS's final rule. We anticipate this alignment may ease compliance burden for parties.

Comment: A commenter asserted that neither VBEs nor VBE participants should be prohibited from entering into non-disclosure agreements with parties to a value-based arrangement because otherwise parties could use information learned in an arrangement against another party in an anticompetitive manner.

Response: Neither the definition of ''value-based arrangement'' nor other safe harbor provisions in this final rule preclude parties to a value-based arrangement from entering into non-disclosure agreements.

Comment: Most commenters opposed our proposal to preclude entities under common ownership from protecting remuneration that they exchange under the value-based safe harbors, whether through a change to the definition of ''value-based arrangement'' or by adding restrictions to one or more of the value-based safe harbors. Commenters asserted that entities under common ownership (*e.g.,* through an integrated delivery system) are often best positioned to improve health outcomes and lower costs through coordinated care. Several commenters also asserted that such a requirement may preclude protection for entities participating in large value-based models, like clinically integrated networks or accountable care organizations. Some commenters also explained that rural and Indian health care providers are frequently operated through common ownership models. Others noted that hospitals in states that restrict direct physician employment often have arrangements with medical groups under common ownership, and another commenter raised concerns about the impact on physician-owned hospitals.

Response: We appreciate commenters' responses. To address commenters' concerns, we are not limiting protection for entities under common ownership in this final rule. We continue to be concerned that there is potential for entities under common ownership to use value-based arrangements to effectuate payment-for-referral schemes, but we also believe that the combinations of safeguards we are adopting in the safe harbors should mitigate these risks. For example, the requirement in the care coordination arrangements safe harbor that the value-based arrangement is commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE, helps to ensure that the arrangements, taken as a whole, are calibrated to achieve the parties' legitimate business purposes.

Comment: A commenter raised concerns about the timing of VBE participants entering into value-based arrangements and recommended that VBE participants not be prevented from providing value-based care to patients before a formal value-based arrangement has been executed. The same commenter recommended that we adopt a 90-day grace period for situations of technical non-compliance related to the timing of VBE participants entering into value-based arrangements.

Response: First, we remind readers that failure to comply with a safe harbor provision (or any attendant, defined term) does not mean that an arrangement is *per se* illegal. Consequently, the value-based safe harbors do not prevent a physician, clinician, or other VBE participant from providing value-based care to patients prior to entering into a value-based arrangement, or at any other time. In addition, the Federal anti-kickback statute, which focuses on the knowing and willful offer, solicitation, payment, or receipt of remuneration in exchange for Federal health care program business, likely would not be implicated by the provision of only clinical care to patients. OIG appreciates that many physicians and others currently furnish value-based care to patients, and nothing in this rule changes their ability to do so. Stakeholders should assess whether arrangements that do not satisfy the definition of ''value-based arrangement,'' as defined in paragraph 1001.952(ee), implicate the statute. Any arrangements that are not value-based arrangements, as defined, would not qualify for protection under the value-based safe harbors, but could qualify under other safe harbors, depending on the facts and circumstances, or they might not need safe harbor protection. As finalized in this rule, a provider or other individual or entity furnishing value-based care may also become a VBE participant, but the value-based arrangements in which it participates might not need safe harbor protection if they do not implicate the statute.

We are not adopting a 90-day grace period to execute value-based arrangements because it is our belief that it is not necessary. When a VBE participant must execute a value-based arrangement to receive safe harbor protection is based on the writing requirements of each safe harbor. For example, in the care coordination arrangements safe harbor as finalized at paragraph 1001.952(ee), the writing that documents the value-based arrangement must be set forth in advance of, or contemporaneous with, the commencement of the value-based arrangement and any material change to the value-based arrangement. Additionally, the writing may be a collection of documents. These flexibilities allow VBE participants to document their participation in a value-based arrangement with minimal burden. A VBE can add a new VBE participant to an existing arrangement in a separate document that becomes part of the collection of documents for that value-based arrangement.

c. Target Patient Population

Summary of OIG Proposed Rule: We proposed to define ''target patient population'' as an identified patient

population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (i) Are set out in writing in advance of the commencement of the value-based arrangement; and (ii) further the value-based enterprise's value-based purpose(s). The proposal would protect only those value-based arrangements that serve an identifiable patient population for whom the value-based activities likely would improve health outcomes or lower costs (or both). In the OIG Proposed Rule, we noted that the definition was not limited to Federal health care program beneficiaries but could encompass, for example, all patients with a particular disease state.

Summary of Final Rule: We are finalizing, without modification, the definition of ''target patient population.''

Comment: Many commenters supported our proposed definition of ''target patient population,'' including our requirement that the identified patient population be selected by the VBE or its VBE participants using ''legitimate and verifiable criteria.'' However, we received numerous comments about the use of the term ''legitimate'' to describe the criteria used to identify the target patient population in the proposed regulatory text, as well as the alternative proposal in the preamble to use the term ''evidence-based.'' Some commenters expressed support for the legitimate criteria standard and stated, for example, that it facilitated a holistic focus on patients' health. This category of commenters generally expressed opposition to the alternative evidence-based standard, arguing that it is too restrictive and would chill innovative value-based arrangements.

Other commenters opposed the use of the term ''legitimate,'' stating that the term is ambiguous. Another commenter suggested that OIG enumerate the types of specific behavior that it wishes to preclude in lieu of using the term ''legitimate''; as an example, the commenter recommended that we state expressly in the definition of ''target patient population'' that it would preclude selection criteria designed to avoid costly or non-compliant patients. Multiple commenters requested that OIG provide additional clarification on the scope and application of the term, such as whether it could encompass criteria based on social determinants of health.

Response: We are finalizing the definition of ''target patient population,'' as proposed, including the ''legitimate and verifiable criteria'' standard. As stated in the OIG Proposed Rule, we used this standard, and in particular, the term ''legitimate,'' to ensure the target patient population selection process is based upon *bona fide* criteria that further a value-based arrangement's value-based purpose(s), and we confirm that, depending on the facts and circumstances, legitimate criteria could be based on social determinants of health, such as safe housing or transportation needs. We are not including an exhaustive list of legitimate or non-legitimate selection criteria because there are various types of criteria that parties could use to select a target patient population; moreover, some criteria may be legitimate for some value-based arrangements but not for others. For example, as we stated in the OIG Proposed Rule, VBE participants seeking to enhance access to, and usage of, primary care services for patients concentrated in a certain geographic region might base the target patient population on ZIP Code or county of residence. In contrast, a value-based arrangement focused on enhancing care coordination for patients with a particular chronic disease might identify the target patient population based on patients who have been diagnosed with that disease. Other VBE participants, such as a social service organization working in conjunction with a pediatric practice, may identify their target patient population using income and age criteria, *e.g.,* pediatric patients who have a household income below 200 percent of the Federal poverty level and who are below the age of 18, in an effort to boost pediatric vaccination rates in a given community.

We are adopting the proposed ''legitimate and verifiable'' standard in lieu of the alternative we proposed, which would have required the use of ''evidence based'' criteria, because we believe requiring ''legitimate and verifiable'' criteria will afford parties comparatively greater flexibility in determining the target patient population and aligns with CMS's definition of the same term.

Comment: We received at least two comments requesting that we expressly state in regulatory text that establishing criteria in a manner that leads to cherry-picking or lemon-dropping would not constitute ''legitimate and verifiable'' selection criteria. These commenters expressed concern that the mere promise by VBE participants not to engage in such behavior would be sufficient to meet the definition of ''target patient population'' and receive safe harbor protection. Another commenter urged that OIG clarify the regulatory language to directly address concerns about cherry-picking or lemon-dropping certain patient populations, in order to avoid unnecessary litigation and legal expense.

Response: In response to the commenters' concerns, we confirm that if VBE participants establish criteria to target particularly lucrative patients (''cherry-picking'') or avoid high-cost or unprofitable patients (''lemon-dropping''), such criteria would not be legitimate for purposes of the target patient population definition. As we stated in the OIG Proposed Rule, if VBE participants selectively include patients in a target patient population for purposes inconsistent with the objectives of a properly structured value-based arrangement, we would not consider such a selection process to be based on legitimate and verifiable criteria that further the VBE's value-based purposes, as required by the definition.[15] We are not adopting further modifications to the proposed definition because the definition's requirement that the criteria be legitimate and verifiable is clear and would not include VBE participants that establish criteria to cherry-pick or lemon-drop patients.

Comment: The vast majority of commenters on this topic opposed our statement in the OIG Proposed Rule that we were considering narrowing the definition of ''target patient population'' to patients with a chronic condition, patients with a shared disease state, or both. Commenters stated that such an approach would restrict the ability of value-based arrangements to adapt to different communities and patient needs and would ignore the importance of preventive care interventions. For example, a commenter highlighted the fact that many underserved and at-risk patient populations are defined not by chronic conditions or shared disease states but instead are identified by socio-economic, geographic, and other demographic parameters that are synonymous with need, poor outcomes, or increased cost.

Response: We are retaining our proposed definition of ''target patient population'' and are not narrowing the definition to include only individuals with chronic conditions or shared disease states. We agree with commenters that were we to narrow the definition, we might exclude underserved and at-risk patient populations who would likely benefit from care coordination and management activities. We also recognize and acknowledge that finalizing our proposed definition will allow for

[15] *See* 84 FR 55702 (Oct. 17, 2019).

value-based arrangements that focus on important preventive care interventions.

Comment: We received a variety of comments on the role of payors in identifying or selecting a target patient population. While some commenters supported requiring payors to select the target patient population, the majority of commenters urged OIG to make their involvement optional. For example, a commenter expressed concern that if OIG were to make payor involvement a requirement, it would impede collaboration between payors and providers. Others expressed uncertainty as to how a requirement that payors select or approve the target patient population would be implemented for Medicare fee-for-service patients and questioned whether CMS would need to affirmatively approve each VBE's or value-based arrangement's target patient population selection criteria.

Response: We are persuaded by commenters that it would not be operationally feasible to require payor involvement in the target patient population selection process. Not all value-based enterprises will include a payor as a VBE participant. Accordingly, while we encourage payor involvement in the target patient population selection process, it is not a requirement in this final rule. It is a requirement that the target patient population be selected by a VBE or its VBE participant.

Comment: We received comments requesting wholesale changes to our proposed definition. For example, a commenter recommended that ''target patient population'' be defined as any set or subset of patients in which the accountable party of a VBE takes significant or full downside risk and is focusing efforts to improve their health and well-being. Another suggested that we eliminate the ''target patient population'' definition altogether and make the value-based safe harbors provider-, not patient-population-, specific.

Response: We are not adopting the commenter's alternative definition of ''target patient population,'' which we did not propose and which would be too narrow to address the use of the term across all of our value-based safe harbors, one of which does not require the VBE participants to take on, or meaningfully share in, any risk. We are also not eliminating the ''target patient population'' definition in favor of making the value-based safe harbors provider-, not patient-population-, specific because orienting the value-based safe harbors around patients is consistent with the goals of value-based care.

Comment: At least two commenters requested that the definition of ''target patient population'' afford parties the flexibility to modify the target patient population over time. Another commenter sought clarification that the definition could include patients retroactively attributed to the target patient population. Another commenter urged OIG to adopt a flexible definition but suggested that if OIG narrows its definition, the term should include underserved patients, such as uninsured and low-income patients; patients with social risk factors; and those with limited English proficiency.

Response: The definition of ''target patient population'' requires, among other criteria, that parties identify a patient population using legitimate and verifiable criteria in advance of the commencement of the value-based arrangement. The selection criteria—not the individual patients—must be identified in advance. Whereas parties seeking to modify their selection criteria may only make such modifications prospectively (and upon amending their existing value-based arrangement), no amendment would be required to attribute patients retroactively to the target patient population, provided such patients meet the selection criteria established prior to the commencement of the value-based arrangement.

Comment: Several commenters sought clarification as to whether a VBE participant's entire patient population could meet the definition of ''target patient population.''

Response: Nothing in the definition precludes the parties to a value-based arrangement from identifying the target patient population as the entire patient population that a VBE participant serves. We recognize that, in limited cases, such broad selection criteria may be appropriate. For example, a VBE may identify all patients in a ZIP Code in order to address an identified population health need specific to that ZIP Code, and it may be that a practice also draws most or all patients from that ZIP Code. Certain specialists, such as geriatricians, might also identify all or most of their patients as needing improved care coordination and management due to their multiple comorbidities and complex care needs. In circumstances where a VBE has assumed full financial risk, as defined in paragraph 1001.952(gg), a VBE might select an even broader target patient population comprised of all patients served by its VBE participants in an effort to more meaningfully control payor costs.

However, we caution that, depending on the value-based arrangement, selecting a target patient population by selecting the parties' entire patient population would need to be closely scrutinized for compliance with the definition to ensure that such broad selection criteria is ''legitimate'' and necessary to achieve the arrangement's value-based purpose.

Comment: Multiple commenters requested that OIG address whether specific categories of patients would be covered by the definition of ''target patient population'' or provide examples of permissible target patient populations. For example, commenters requested confirmation that a target patient population could include all patients covered by a certain payor, such as Medicare. Another commenter expressed concern that transient patient populations who may have different providers in different geographic locations would not be covered by the definition.

Response: As described above, a target patient population based on patients who have been diagnosed with a particular disease could, based on the specific selection criteria, be a permissible target patient population. Whether a particular patient population, including transient patient populations with different providers in different geographic locations, meets the definition of ''target patient population'' is a fact-specific determination that turns on whether the VBE participants used legitimate and verifiable selection criteria and met the other requirements set forth in the definition. While there may be circumstances, *e.g.,* the assumption of full financial risk (as defined in paragraph 1001.952(gg)), where a VBE identifies all of the patients of a particular payor as the target patient population, we caution that relying on this criterion, without sufficient justification for such a broad approach, could raise questions regarding whether it is legitimate or, instead, is a way to capture referrals of, for example, Medicare business.

d. Value-Based Activity

Summary of OIG Proposed Rule: We proposed to define ''value-based activity'' as any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (i) The provision of an item or service; (ii) the taking of an action; or (iii) the refraining from taking an action. We further proposed that the making of a referral is not a value-based activity.

Summary of Final Rule: We are finalizing, without modification, the definition of ''value-based activity.''

OIG's final definition of ''value-based activity'' differs from the definition in the CMS Final Rule because CMS does not specify that the making of a referral is not a value-based activity. As explained in CMS's final rule, CMS has not included a comparable restriction because of the physician self-referral law's separate definition of referral.

Comment: Many commenters supported the definition of ''value-based activity,'' as proposed. Several commenters asked OIG to clarify the definition of ''value-based activity'' further by specifying what activities would or would not qualify as value-based; how VBEs would demonstrate that the activities they select are reasonably designed to achieve a value-based purpose; and what it means to refrain from taking an action. A few commenters asked whether providing services to patients constitutes a value-based activity.

Response: The term ''value-based activity'' is intended to be broad and to include the actions parties take or refrain from taking pursuant to a value-based arrangement and in furtherance of a value-based purpose. By way of example, where a VBE participant offeror provides a type of health technology under a value-based arrangement for the recipient to use to track patient data in order to spot trends in health care needs and to improve patient care planning, the provision of the health technology by the offeror would constitute a value-based activity, and the use of the health technology by the recipient to track patient data would constitute a value-based activity. If the remuneration a VBE participant offeror provides is care coordination services, a value-based activity might be the recipient working with a care coordinator provided by the offeror to help transition certain patients between care settings. Giving something of value to patients, such as a fitness tracker, also may constitute a value-based activity if doing so is reasonably designed to achieve a value-based purpose. However, we note that, where VBE participants exchange remuneration that the recipient VBE participant then transfers to its patients (for example, where one VBE participant provides fitness trackers to another VBE participant, who in turn furnishes the fitness tracker to the patient), the care coordination arrangements safe harbor would be available only to protect the remuneration exchanged between the VBE participants. The parties may look to the patient engagement and support safe harbor to protect the remuneration from the VBE participant to the patient. An inaction that constitutes a value-based activity might be refraining from ordering certain items or services in accordance with a medically appropriate care protocol that reduces the number of required steps in a given procedure. This final rule does not prescribe how parties prove that a particular action or inaction constitutes a value-based activity. Similarly, it is incumbent on the parties to demonstrate that they selected value-based activities that are reasonably designed to achieve a value-based purpose. Both of these analyses would be fact-specific determinations.

Comment: A commenter asked whether this definition could be combined with the definition of ''value-based purpose'' to reduce administrative complexity. Another commenter asserted that the definition of ''value-based activity'' should recognize the importance of maintaining patient care and outcomes at an acceptable level.

Response: We are finalizing the definition of ''value-based activity,'' as proposed, and are not combining it with the definition of value-based purpose. In our view, separate definitions do not increase administrative complexity, and we have coordinated terminology with CMS to reduce complexity. We are not changing the definition of ''value-based activity'' to include the maintenance of patient care and outcomes at an acceptable level because the definition of ''value-based activity'' is tied to the definition of ''value-based purpose,'' which sets forth four purposes toward which parties may be striving pursuant to value-based arrangements. While maintaining patient care and outcomes at an acceptable level is clearly desirable, we note that doing so, without more, is not one of the four value-based purposes needed to establish a VBE for this rulemaking.

Comment: Many commenters supported the alternate proposal to expressly exclude any activity that results in information blocking from the definition of ''value-based activity.'' A commenter recommended that, if OIG expressly excludes information blocking from the definition of ''value-based activity,'' OIG should do so by referencing only statutory definitions and requirements in the Cures Act and not those set forth in ONC's proposed rule, whereas another commenter noted that, as an alternative to expressly excluding information blocking activities in the definition of ''value-based activity,'' OIG could assume that information blocking will no longer be tolerated and leave the enforcement of information blocking restrictions to the regulation finalized in 45 CFR part 171.

Response: The final rule does not include the proposed language regarding information blocking. Regardless of whether parties seek safe harbor protection, if parties to value-based arrangement are subject to the regulations prohibiting information blocking, they must comply with those regulations. This final rule does not change the individuals and entities subject to the information blocking prohibition in 45 CFR part 171.

Comment: A commenter expressed concern that the definition of ''value-based activity'' is too broad and vague and that VBE participants will characterize abusive remuneration-for-referral arrangements as value-based activities. The commenter suggested requiring that an activity achieve a value-based purpose, as opposed to requiring that an activity be reasonably designed to achieve a value-based purpose.

Comments varied regarding how to interpret whether an activity is ''reasonably designed'' to achieve a value-based purpose. While a commenter supported interpreting ''reasonably designed'' to mean that the value-based activities are expected to further one or more value-based purposes, another commenter suggested that such a determination be based on all relevant facts and circumstances. Other commenters recommended establishing a rebuttable presumption that value-based activities are reasonably designed to meet their stated value-based purpose. Another commenter urged OIG to require that value-based activities be directly connected to and directly further the coordination and management of care; not interfere with the professional judgment of health care providers; not induce stinting on care; and not incentivize cherry-picking lucrative or adherent patients or lemon-dropping costly or noncompliant patients.

Lastly, while at least one commenter supported a requirement for parties to use an evidence-based process to design value-based activities, several commenters opposed this requirement, stating that such a standard would be too rigorous and would restrict innovative activities.

Response: We are finalizing our definition as proposed. We intentionally crafted a broad definition of ''value-based activity'' to encourage parties to innovate when developing these activities. For that reason, we are not requiring that an activity achieve a value-based purpose but rather are requiring that a value-based activity be reasonably designed to achieve a value-based purpose. By ''reasonably

designed,'' we mean that parties should fully expect the value-based activities they develop to further one or more value-based purposes. Because any such determination would be fact specific, we do not believe it is appropriate to establish a rebuttable presumption that value-based activities are reasonably designed to meet their stated value-based purpose, as suggested by a commenter.

We note that, while this definition offers parties significant flexibility, it is not intended to facilitate parties' attempts to mask fraudulent referral schemes presented under the guise of a value-based activity. We highlight that the definition provides that merely making a referral, without more, is not a value-based activity for purposes of this rule.

Lastly, we do not intend for the value-based safe harbors to protect activities that inappropriately influence clinical decision-making, induce stinting on care, or lead to targeting particularly lucrative patients or avoiding high-cost or unprofitable patients. We have incorporated a range of safeguards in the safe harbors that are designed to guard against these abusive practices. In light of these safeguards, we do not believe that revisions to the definition of ''value-based activity'' are necessary.

Comment: Several commenters asked OIG to clarify what differentiates care coordination services from inappropriate referrals and to modify the definition to make clear that a referral could be one part of a broader value-based activity. Some commenters expressed concern that the definition of ''value-based activity'' prohibits safe harbor protection for value-based arrangements in which payments or other remuneration depend, in part, on referrals made within a preferred provider network. A commenter asked whether documenting that a referral was made and the reason for the referral would constitute a ''value-based activity.''

Response: Making referrals, or documenting reasons for referrals, would not constitute value-based activities. Parties to a value-based arrangement may make referrals and document the reasons for the referrals as part of a value-based arrangement without losing safe harbor protection under an applicable safe harbor, but the parties also must be performing one or more value-based activities. Thus, making referrals or documenting reasons for referrals, without also engaging in a value-based activity, would not be sufficient to meet the requirements of the definition because making referrals is not itself a value-based activity. Absent at least one value-based activity, parties would not have a viable value-based arrangement and would thus not be eligible for any of the value-based safe harbors.

The provision excluding referrals from the scope of value-based activities is not intended to interfere with preferred provider networks; rather, we intend to require parties to engage in activities other than making referrals, such as coordinating care plans across providers for a target patient population, to be eligible for safe harbor protection.

e. VBE Participant

Summary of OIG Proposed Rule: We proposed to define ''value-based enterprise participant'' or ''VBE participant'' as an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. Based on historical concerns regarding fraud and abuse risk and our understanding that certain types of entities were less critical to coordinated care, we proposed that the term ''VBE participant'' would not include a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies; or a laboratory. We stated that we were considering and thus seeking comments as to whether other types of entities should also be ineligible, including pharmacies (including compounding pharmacies), PBMs, wholesalers, distributors, and medical device manufacturers. As a result of this proposed definition, these entities would not be able to participate in VBEs or seek protection under the value-based safe harbors or the patient engagement and support safe harbor.

We stated our intent to offer safe harbor protection for remuneration exchanged by companies that offer digital technologies to physicians, hospitals, patients, and others for the coordination and management of patients and their health care. We recognized that companies providing these technologies may be new entrants to the health care marketplace or may be existing companies such as medical device manufacturers. We explained that we would consider for the final rule several ways to effectuate our desire to ensure safe harbor protection for remuneration exchanged by health technology companies, including through modifications to the value-based terminology; distinctions drawn among entities based on product-types or other characteristics; or modifications to the safe harbors themselves.

In the OIG Proposed Rule, we considered and solicited comments on potential additional safeguards to incorporate into the value-based safe harbors to mitigate risks of abuse that might be presented should a broader range of entities be eligible to enter into value-based arrangements, including restrictions on the parties' use of exclusivity and minimum purchase requirements.

For additional background and rationale for our proposals, we refer readers to the discussion of the definition of ''VBE participant'' in the OIG Proposed Rule.[16]

Summary of Final Rule: We are finalizing, with modifications, the definition of ''VBE participant.'' We are finalizing our proposed policy that a ''VBE participant'' is an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. We are not finalizing our proposed regulatory text to make certain entity types ineligible under the definition of ''VBE participant.'' However, we are finalizing our proposed policy to make certain entities ineligible for safe harbor protection under the value-based safe harbors and the patient engagement and support safe harbor (see section III.B.e.ii for details). We are also finalizing our proposed policy to protect some arrangements involving digital health technologies provided by certain entities that would otherwise be ineligible for safe harbor protection (see section III.B.e.iii).

To effectuate these objectives, we are finalizing a different approach to the definition of ''VBE participant'' in the following four respects.

First, we are revising the definition of ''VBE participant'' to allow all types of individuals (other than patients) and entities to be VBE participants. This revision makes our definition more similar to CMS's corresponding definition and removes a potential impediment to existing organizations that wish to qualify as VBEs but may include types of entities we proposed to disallow as VBE participants. We now define the term ''VBE participant'' to mean an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient when acting in their capacity as a patient. This does not, however, mean that every VBE participant will receive protection under the applicable safe harbors; it is intended to avoid a barrier to the formation and operation of the VBE itself. The new definition also makes clear that patients cannot be VBE participants, consistent with our intent in the OIG Proposed Rule. Entities seeking safe harbor protection for

[16] 84 FR 55703–06 (Oct. 17, 2019).

remuneration provided to patients should look to the patient engagement and support safe harbor for protection, not to the value-based safe harbors.

Second, rather than making certain entities ineligible under the definition of ''VBE participant,'' as described in the OIG Proposed Rule, the final rule takes a different approach to achieve the proposed policy to make some entities ineligible for safe harbor protections. In the final rule, within each value-based safe harbor (and the patient engagement and support safe harbor, as discussed further at section III.B.6), we identify entities that are not eligible to rely on the safe harbor to protect remuneration exchanged with a VBE or other VBE participants. Specifically, the value-based safe harbors each include an ineligible entity list. Remuneration exchanged by entities on the list in each safe harbor is not eligible for protection under the safe harbor.

The following entities are included on the ineligible entity lists in all of the value-based safe harbors: (i) Pharmaceutical manufacturers, distributors, and wholesalers (referred to generally throughout this preamble as ''pharmaceutical companies''); (ii) PBMs; (iii) laboratory companies; (iv) pharmacies that primarily compound drugs or primarily dispense compounded drugs (sometimes referred to generally in this rule as ''compounding pharmacies''); (v) manufacturers of devices or medical supplies; (vi) entities or individuals that sell or rent DMEPOS, other than a pharmacy or a physician, provider, or other entity that primarily furnishes services, all of which remain eligible (referred to generally throughout this preamble as ''DMEPOS companies''); and (vii) medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies (for example, some physician-owned distributors).

Third, we proposed to address safe harbor protection for technology companies by considering how and whether they could fit in the definition of a VBE participant. In the final rule, we instead focus on safe harbor protection for the remuneration exchanged with or by them. Specifically, the care coordination arrangements safe harbor at paragraph 1001.952(ee) permits protected remuneration in the form of digital health technology (or other technologies) exchanged between VBE participants eligible to use the safe harbor. To address protection under this safe harbor for arrangements with manufacturers of devices and medical supplies and DMEPOS companies that involve digital health technology, we have taken a tailored, risk-based approach. Manufacturers of devices and medical supplies and DMEPOS companies that are otherwise ineligible for the value-based safe harbors are nonetheless eligible to rely on the care coordination arrangements safe harbor for digital health technology arrangements that meet all safe harbor conditions, including an additional one. Under this pathway, we define ''limited technology participant'' to include, as further discussed below, a manufacturer of a device or medical supply or a DMEPOS company that is a VBE participant that exchanges digital health technology with another VBE participant or a VBE.

Our revised approach effectively divides the universe of VBE participants into three categories: (i) VBE participants that are eligible to rely on the value-based safe harbors for all types of arrangements that meet safe harbor conditions; (ii) limited technology participants that are only eligible to rely on the care coordination arrangements safe harbor for arrangements involving digital health technology; and (iii) VBE participants that are ineligible to rely on any of the value-based safe harbors for any types of arrangements. The first category is the default category, capturing all entities and individuals who are not expressly included in the second and third categories. For a discussion of ineligible entities and the treatment of digital health technology under the patient engagement and support safe harbor, see the discussion in section III.B.6.b and f. For a discussion of ineligible entities under the personal services and management contracts and outcomes-based payments safe harbor, see sections III.B.10.c and d.

Fourth, to address heightened risk of fraud and abuse and to help ensure that protected remuneration meets the policy goals of this rulemaking, we require that the exchange of digital health technology by a limited technology participant is not conditioned on any recipient's exclusive use of, or minimum purchase of, any item or service manufactured, distributed, or sold by the limited technology participant. Rather than finalizing this condition in the definition of a VBE participant as contemplated in the OIG Proposed Rule, this is now a separate condition at paragraph 1001.952(ee)(8).

i. Approach To Defining ''VBE Participant''

Comment: While we received some support for our proposed definition of ''VBE participant,'' many commenters expressed concerns regarding the proposed categorical exclusion of certain entities. Several commenters asserted that no entities should be precluded from participating in value-based arrangements, and many encouraged us to adopt an alternative approach based on product type, company structure, fraud risk, the legitimacy of the party's objectives and deliverables, or other features. Commenters also noted that many existing value-based arrangements include entities that we were considering making ineligible to be a VBE participant. Another commenter asserted that allowing entities to participate as VBE participants will incentivize them to understand and expand cost mitigation strategies, which will help lower the cost of care. Others emphasized that the health care industry is highly dynamic, with frequent corporate transactions. They expressed concern that an entire value-based arrangement may inadvertently fall out of compliance with a safe harbor because one VBE participant acquires an entity that is not eligible to be a VBE participant. Other commenters supported placing exclusions directly in the safe harbor, rather than in the definition, to create greater flexibility. A commenter recommended that OIG create a new defined term, ''VBE partner,'' to designate individuals and entities that provide social determinants of health support and services at the direction of a VBE or VBE participant but are not themselves part of the VBE. According to the commenter, this would allow many services providers, such as rideshare companies, social service organizations, and foodbanks that already have direct partnerships with a VBE participant to participate in protected arrangements without having to become full participants in a VBE.

Response: We recognize that there may be benefits to allowing all entities to participate as VBE participants, and we also appreciate the concerns raised by these commenters. In response to comments, our revised approach, in which any individual (other than a patient) or entity is eligible to be a VBE participant, will alleviate many of them.

In the OIG Proposed Rule, we described several approaches we were considering for determining entities that could be VBE participants in the final rule and, as such, able to rely on the value-based safe harbors. We are adopting the approach of making entities ineligible under the value-based safe harbors rather than through the definition of ''VBE participant.'' This approach allows for closer alignment with CMS's terminology, addresses concerns about unintended impacts of

otherwise ineligible VBE participants on the makeup of a VBE, and does not impede VBEs from engaging in a wide range of value-based payment and delivery arrangements, regardless of whether those arrangements qualify for safe harbor protection. By addressing eligibility in specific safe harbors rather than through the VBE participant definition, the final rule creates flexibility for all health care stakeholders to be part of a VBE and reduces any need for parties to form VBEs structured solely for purposes of using the new safe harbors. This approach also facilities our final policy on providing safe harbor protection for digital health technology arrangements with limited technology participants (described in more detail later).

While all entities are eligible to be VBE participants, each value-based safe harbor and the patient engagement and support safe harbor incorporates a list of entities that are ineligible for safe harbor protection. As discussed in greater detail below, we determined which entities should be ineligible based on multiple factors, including the extent to which the entities are involved in front line care coordination and program integrity concerns.

Under this final rule, a VBE will not cease to meet the definition of a ''VBE'' solely because a VBE participant merges with or acquires a different type of entity or develops a new business line. Nor would a VBE participant necessarily cease to be eligible to use a value-based safe harbor solely because it acquires an entity that is not eligible. To the extent a transaction causes a VBE participant to become an ineligible entity, the safe harbor would no longer be available to protect any remuneration exchanged by that entity under a value-based arrangement.

Consistent with the OIG Proposed Rule discussion of alternatives for determining which entities are eligible and ineligible for safe harbor protection, we have adopted a risk-based, policy-focused approach to determine the scope and applicability of the final safe harbors. With respect to the ineligible entities in the value-based safe harbors, those entities are identified based on a number of attributes, including the products and services they offer, how they structure their business, and the extent to which they are on the front line of care coordination and treatment decisions. In the care coordination arrangements safe harbor, we further distinguish among entities in part on the basis of product or arrangement type. These considerations are directly related to the goals of the Regulatory Sprint and the design of the conditions in each safe harbor to protect against fraud and abuse.

With respect to the recommendation that we create a new category of ''VBE partners,'' we are not adopting this suggestion. The proposed and final value-based safe harbors were and are designed for value-based arrangements between VBEs and one or more of their VBE participants or between or among VBE participants in the same VBE. The ability to determine with specificity which individuals and entities are in a VBE and which are not enhances transparency, certainty, and accountability for arrangements seeking safe harbor protection. Social services agencies, rideshare companies, foodbanks, and others are eligible to be VBE participants if they wish for their arrangements to be eligible for protection under the value-based safe harbors. If for any reason they do not wish to be VBE participants or cannot become VBE participants, nothing in this rule would prevent them from engaging in care coordination or other arrangements that do not fit in these new safe harbors. In some cases, the arrangements might fit in other safe harbors, such as the local transportation safe harbor (*e.g.,* for rideshare arrangements). For other arrangements, the parties would need to review the specific facts of the arrangement, including the intent of the parties, to ensure compliance with the Federal anti-kickback statute.

Notably, if there is nothing of value given by a social services agency or foodbank, for example, to an individual or entity in exchange for or to induce or reward referrals of items or services for which payment may be made under a Federal health care program, the statute would not be implicated. We would expect this to be the case for many social services agencies, foodbanks, and other entities that provide social services, food, or other supports to patients and (1) do not bill Federal health care programs and (2) do not refer Federal health care patients to health care providers for reimbursable services or otherwise recommend or arrange for such services.

Comment: Several commenters requested that we either confirm in the preamble, or revise the definition of ''VBE participant'' to state expressly, that certain types of entities or providers, such as retail health clinics, charitable clinics and pharmacies, federally qualified health centers, credentialed orthotists and prosthetists, payors, physician shareholders and employees of medical groups, and non-traditional health care entities, among others, qualify as VBE participants.

Response: Under our revised definition of a ''VBE participant,'' all types of entities can be VBE participants. Entities would need to refer to the specific safe harbors to determine whether they are eligible to rely on the safe harbor.

Comment: Some commenters noted that CMS's proposed value-based terminology does not make any entities ineligible to be a VBE participant.

Response: Our final definition of ''VBE participant'' is aligned with CMS's definition, with the exception of a detail around the use of the term ''individual'' in our rule and ''person'' in CMS's rule and our policy that patients may not be VBE participants. The ''individual'' versus ''person'' verbiage relates to the difference in language used elsewhere in the two regulatory schemes and promotes overall consistency across safe harbors for OIG and exceptions for CMS.

For clarity, we have included an express statement in regulatory text, not included in CMS's definition, carving patients out of the definition of ''VBE participant.'' This carve out would extend to the patient's family members or others acting on the patient's behalf, consistent with the approach we take elsewhere in this final rule with respect to the coordination and management of care with patients. The context and framework of the value-based provisions in the OIG Proposed Rule made clear that we did not intend patients to be VBE participants who could engage in value-based arrangements under the value-based safe harbors. In the proposed regulations, we described VBE participants as engaging in at least one value-based activity as part of a VBE and being part of at least one value-based arrangement to provide at least one value-based activity for a target patient population. The role of VBE participants in health care business activities of VBEs is not a role assumed by patients and families, who play a critical role in patient care in other ways. Our modification in the final rule clarifies this point.

Under our proposed rule and this final rule, VBE participants providing remuneration to patients would look to the patient engagement and support safe harbor for protection, not to the value-based safe harbors. Our reference to ''individuals'' in the proposed definition was meant to capture physicians, nurses, and other practitioners, providers, and suppliers in the health care ecosystem involved in caring for patients. Our revised regulatory text recognizes that all individuals will likely be a patient at one point or another and that our carve-

out of patients is limited to patients when acting in their capacity as patients. In other words, a physician remains eligible to be a VBE participant even if he or she is also sometimes a patient.

Comment: Several commenters encouraged us to consider requiring additional safeguards within each safe harbor to address concerns regarding particular types of entities, rather than categorical exclusions from the definition of ''VBE participant.'' Others opposed applying additional safeguards, believing the existing safeguards in the OIG Proposed Rule were sufficient for all types of entities.

Response: For reasons noted above, including input from comments, we are not adopting categorical exclusions from the definition of ''VBE participant.'' Instead, relying on factors such as fraud and abuse risk and level of participation in front line care of patients, we identify certain entities as ineligible for protection in specified safe harbors, and include a tailored additional condition for certain high-risk entities engaged in arrangements involving digital health technology. The entities that are ineligible for protection and the rationale for carving them out are addressed in greater detail below in response to comments specific to these entities. We also provide greater detail below regarding the entity-specific safeguard we are adopting in the care coordination arrangements safe harbor for arrangements involving digital health technology.

Comment: Several commenters challenged OIG's assertion that its history of law enforcement activities involving certain types of entities should form the basis for whether entities are entitled to protection under the value-based safe harbors. Some of these commenters noted that many other types of parties, including hospitals and physicians, have likewise been the subject of enforcement actions. Others asserted that the past bad acts of a few should not dictate the future compliance risks of the many, particularly where many of the historic enforcement actions resulted in settlements without admission of guilt, rather than actual convictions.

Response: We agree with the commenters that the bad acts of the few should not dictate the compliance risks of the many. We proposed and are finalizing new safe harbors intended to aid the majority of stakeholders that are honest and trying to do the right thing for patients and the health care system. The fact that an entity type is categorically ineligible for safe harbor protection does not mean that all entities in the category are bad actors. In crafting the value-based safe harbors, we have balanced new flexibility under a criminal statute with protections where we identified elevated risk of fraud and abuse. Our experience investigating fraud and enforcing the anti-kickback statute necessarily informs our approach to establishing safe harbors for specific payment practices consistent with the criteria set forth at section 1128D(a)(2) of the Act (safe harbor authority under the Federal anti-kickback statute). Our enforcement and oversight work offer insights into common fraud schemes, trends, and methods used by bad actors to circumvent rules. In bringing this experience to bear, we considered multiple types of entities and arrangements that have been the subject of our work. The risk of fraud and abuse is one factor in determining the types of entities eligible for protection under the safe harbors. Others include, for example, the degree of participation of the entity type in the care coordination arrangements that are central to this rulemaking and the level of need for the entity type to have safe harbor protection to effectuate the policy goals of the Regulatory Sprint. We acknowledged in the OIG Proposed Rule and reiterate here that the new safe harbors do not address all beneficial value-based arrangements.

Comment: A commenter requested confirmation that the definition of ''VBE participant'' would not bar an integrated delivery system from creating a value-based arrangement within its own system.

Response: There is nothing in the definition of ''VBE participant'' that would preclude an integrated delivery system from creating a value-based arrangement within its own system.

Comment: A commenter requested that OIG make clear that the safe harbors do not preclude entities that are ineligible to be VBE participants from contributing to value-based activities or contracting with VBEs.

Response: We believe our revised approach, where all entities are eligible to be a VBE participant, addresses the commenter's concern. We wish to clarify further that the value-based safe harbors do not prohibit the VBE from entering into contractual arrangements with any type of entity, including an entity that is not a VBE participant. However, an entity that is not a VBE participant will not be eligible for safe harbor protection. Remuneration exchanged by certain types of entities, including non-VBE participants and VBE participants on the carve-out list, will not be protected by a value-based safe harbor, and parties would need to look to other safe harbors to the extent they want to protect it.

Comment: A commenter supported the fact that the proposed definition of ''VBE participant'' did not require VBE participants to be equity owners of the VBE.

Response: We did not propose requirements related to equity ownership of VBEs. However, we note that the value-based safe harbors do not protect remuneration in the form of ownership interests or returns on those interests.

Comment: A commenter recommended that, if OIG finalizes the definition of ''VBE participant'' as proposed, it also modify the advisory opinion process so that opinions may be relied upon by parties other than just the requesting party.

Response: Modifying the OIG advisory opinion process is beyond the scope of this rulemaking.

ii. Entities Ineligible for Safe Harbor Protection

The value-based safe harbors deem certain entities ineligible for safe harbor protection. Those entities are: Pharmaceutical companies; PBMs; laboratory companies; compounding pharmacies; manufacturers of devices or medical supplies; DMEPOS companies; and medical device distributors and wholesalers. Notwithstanding, under the care coordination arrangements safe harbor (paragraph 1001.952(ee)), manufacturers of devices and medical supplies and DMEPOS companies are eligible as limited technology participants to protect certain digital health technology arrangements to allow them to participate in such arrangements, along with other types of eligible VBE participants. As explained in more detail below, these distinctions are rooted in a functional approach focusing on the items, services, and products furnished by the different entity types and their roles in care coordination, along with assessment of program integrity risk based on enforcement experience. We aim to balance flexibility to achieve the Regulatory Sprint goals with protection against fraud and abuse.

This preamble section responds to comments about each of these entity types in turn. The outcomes-based payments safe harbor at paragraph (d)(2) and the patient engagement and support safe harbor at paragraph 1001.952(hh) reference these same entities and rely on the same definitions when doing so.

(a) Pharmaceutical Manufacturers, Wholesalers, and Distributors

Comment: Many commenters agreed with our proposal not to include pharmaceutical manufacturers in the definition of ''VBE participant.'' These commenters articulated a variety of supporting rationales, including that manufacturers are less involved in care coordination and present an increased risk of abusive arrangements. Many other commenters encouraged OIG to allow pharmaceutical manufacturers to participate as VBE participants, arguing, among other things, that manufacturers are well-positioned to contribute to value-based arrangements and that their participation is essential given the role of medications in improving care. For example, commenters noted that manufacturers can leverage data analytics and technology to improve both outcomes measurement and care management. Several commenters also emphasized that manufacturers can provide a variety of services relating to medication adherence, which may play a central role in value-based arrangements by managing care and reducing costs. Commenters also emphasized that manufacturers often know their product best and are thus in an ideal position to bring value through continued involvement.

Response: Under the revised framework we are adopting in this final rule, pharmaceutical companies can be VBE participants, and existing VBEs that include pharmaceutical companies do not need to be restructured for purposes of this rulemaking. However, we are effectuating our intent that pharmaceutical companies would not be eligible to use the value-based safe harbors by including pharmaceutical companies on the ineligible entity list in each safe harbor. We agree with the commenters that pharmaceutical manufacturers are not as likely as other entities to be involved with front line care coordination, and we remain concerned, as noted in the OIG Proposed Rule, about the potential for pharmaceutical manufacturers to use the value-based safe harbors to protect arrangements that are intended to market their products or inappropriately tether clinicians to the use of a particular product rather than as a means to create value by improving the coordination and management of patient care. As a result, protection under the value-based safe harbors does not extend to remuneration that pharmaceutical manufacturers exchange with other VBE participants.

We recognize that pharmaceutical manufacturers can play important roles in delivering efficient, high quality care to patients, including, for example, through medication adherence programs and data sharing. However, like any arrangement that does not qualify for a safe harbor, such arrangements would need to be analyzed for compliance with the anti-kickback statute based on their specific facts, including the intent of the parties. They are not eligible for protection under these new safe harbors.

As noted in the OIG Proposed Rule, we continue to consider the role of pharmaceutical manufacturers in coordinating and managing care as well as how to address value-based contracting and outcomes-based contracting for pharmaceutical products and medical devices, including devices that do not meet the definition of ''digital health technology'' under this rule.

Comment: Many commenters encouraged OIG to allow pharmaceutical manufacturers to participate in value-based contracting arrangements where they take on financial risk. Several of these commenters specifically supported arrangements where payment for prescription drugs is tied to clinical endpoints or patient outcomes, such as where a manufacturer agrees to provide a full or partial refund on a product if a course of treatment fails to achieve the desired outcome. Other commenters expressed skepticism about value-based contracting and encouraged OIG to adopt safeguards to protect against potentially abusive arrangements. Another commenter suggested that OIG adopt manufacturer-specific safe harbors with a sliding scale of risk. Among commenters who supported protecting value-based contracting, many raised concerns that existing best price requirements in the Medicaid Drug Rebate Program operate as an actual or perceived impediment to these types of arrangements and encouraged OIG to work with CMS to resolve these issues.

Response: We did not propose either a value-based contracting safe harbor or pharmaceutical manufacturer-specific safe harbors with a sliding scale of risk in this rulemaking. With respect to commenters' concerns regarding the potential impact of value-based contracting on Medicaid best price reporting obligations, those issues are outside the scope of this rulemaking.

Comment: A trade association representing pharmaceutical manufacturers requested that OIG clarify that any exclusion of pharmaceutical manufacturers from the value-based safe harbors is not intended to discourage manufacturers from participating in arrangements for value-based care. Another commenter asserted that pharmaceutical manufacturers' participation in care coordination may be necessary with the advancement of therapies like personalized cell therapies, which use a modified version of the patient's own cells to treat disease. A commenter recommended that a nonprofit generic drug company that addresses drug shortages in the marketplace be permitted to participate as a VBE participant, even if pharmaceutical manufacturers are not eligible.

Response: Nothing in this final rule is intended to discourage pharmaceutical manufacturers from participating in arrangements for value-based care. Under this rule as finalized, a pharmaceutical company can be a VBE participant collaborating with others in a VBE. Nothing prevents a pharmaceutical company (or any other type of entity) from participating in care coordination arrangements, but remuneration exchanged by the pharmaceutical company under those arrangements would not qualify for protection under the value-based safe harbors. For example, we appreciate that pharmaceutical companies can work to address shortages in the marketplace and could enter into arrangements with a VBE and VBE participants to address those issues. Those arrangements would need to be analyzed based on their specific facts for compliance with the anti-kickback statute. The failure to fit in a safe harbor does not mean an arrangement is unlawful under the anti-kickback statute. Moreover, safe harbor protection is irrelevant to the extent that an arrangement does not implicate the anti-kickback statute. We reiterate that parties may structure arrangements to meet other safe harbors, such as the safe harbor for personal services arrangements or the warranties safe harbor and may also use OIG's advisory opinion process to the extent they want prospective protection for arrangements they wish to undertake.

Comment: Commenters were divided on whether pharmaceutical wholesalers and distributors should be eligible to be VBE participants. Some stated that these entities present the same types of risks and concerns that manufacturers present (*e.g.,* inappropriately increased costs to Federal health care programs) and should be ineligible for the same reasons. Many commenters who supported allowing manufacturers to be VBE participants also supported allowing wholesalers and distributors to be VBE participants.

Response: All entities are permitted to be VBE participants under this final rule. However, remuneration exchanged by pharmaceutical companies, including distributors and wholesalers, is not protected by the value-based safe harbors, consistent with our proposal to make them ineligible. We adopt this policy for reasons comparable to those for making manufacturers ineligible, including that wholesalers and distributors are less likely to have a direct role in front line patient care coordination. We are not persuaded that pharmaceutical distributors' and wholesalers' indirect role in support of coordinating care warrants protection under the value-based safe harbors.

(b) Pharmacy Benefit Managers

Comment: In response to our consideration in the OIG Proposed Rule related to PBMs, several commenters urged us to make PBMs ineligible to be VBE participants. A few of these commenters supported making PBMs ineligible based on concerns about potentially abusive PBM practices that they believe affect drug prices and limit treatment options for patients. Other reasons that commenters provided include that PBMs are not front-line health providers and protecting arrangements involving PBMs in the value-based safe harbors may inappropriately affect treatment decisions by health care practitioners. A commenter also suggested we require VBEs that establish relationships with PBMs to include information regarding such relationships in relevant VBE documents and reports.

Conversely, many commenters urged us to allow PBMs to be eligible to be VBE participants. Commenters asserted that PBMs are engaged in a number of activities that relate to care coordination and the value-based purposes we proposed, including, for example, developing formularies to select drugs based on relative value, leveraging health information technology to assist in coordinating care and managing benefits, and operating a variety of care coordination programs, such as medication adherence, medication therapy management, and chronic condition education. Commenters emphasized the role that PBMs play with respect to controlling pharmaceutical costs and promoting quality by ensuring clinical efficacy. Several commenters sought to distinguish PBMs from pharmaceutical manufacturers, noting that pharmacy benefit managers have no connection to any particular drug product and do not rely on prescriptions or referrals for any particular product. Another commenter asserted that PBMs are well-suited to enter into risk bearing arrangements because their business model already involves helping their clients manage insurance risk.

Response: As described above, all types of entities are eligible to be VBE participants under this final rule. However, we are finalizing our proposal for PBMs to be ineligible to rely on the value-based safe harbors to protect remuneration.

PBMs are less likely to be on the front line of care coordination and treatment decisions in the same way as other types of VBE participants eligible to use the value-based safe harbors. We recognize and appreciate the information that commenters provided on the role that PBMs serve in supporting value-based care and coordinating care, for example, by designing formularies based on relative value, using their expertise to improve medication adherence, and managing insurance risk. However, we are not persuaded that PBM's indirect role in support of coordinating care or managing risk warrants protection under the value-based safe harbors, which focus significantly on the coordination and management of patient care. PBMs play a unique role in establishing benefit networks and associated management services connected to payors, pharmaceutical manufacturers, and pharmacies. As a result, PBM arrangements raise different program integrity issues from the types of value-based arrangements contemplated by this rulemaking and would likely require different safeguards.

Under the final rule, PBMs, as with all individuals (except for patients) and entities, are eligible to be VBE Participants. This will allow PBMs to continue supporting value-based care, even though they are not eligible to rely on the value-based care safe harbors. We note that some PBMs' value-based activities may not implicate the Federal anti-kickback statute, depending on the specific facts and circumstances of each arrangement. Parties may also use OIG's advisory opinion process to the extent they want prospective protection for arrangements involving the exchange of remuneration with PBMs.

In response to the suggestion that VBEs that have relationships with PBMs be required to document and disclose such relationships, the value-based definitions have relevant documentation and oversight conditions, including a requirement that the VBE governing documentation describe how the VBE participants intend to achieve the VBE's value-based purpose(s).

We recognize that many PBMs are owned, affiliated with, or under common ownership structures with other entities, particularly payors and health benefit plans. Considering the role that payors have in the substantial downside risk and full financial risk safe harbors, it is important to note that payors would be eligible for safe harbor protection even if they own, are affiliated with, or are under common ownership with a PBM. Additionally, a payor would be eligible for safe harbor protection if it does not contract out its pharmacy benefit management services and instead performs those functions as part of its administration of a health benefit plan more broadly. We would consider the PBM functions, in that context, to be ancillary to the payor's predominant or core business, which is administering a health benefit plan. Thus, such a payor would not be considered to be a PBM for purposes of eligibility for protection under the value-based safe harbors, notwithstanding the fact that it performs some PBM activities. See the discussion at section III.B.2.e.5, below regarding entities with multiple lines of business for further details regarding the predominant or core business standard.

(c) Laboratory Companies

Comment: While some commenters supported our proposal to make clinical laboratories ineligible to be VBE participants or suggested that we only allow them to be VBE participants if we included additional safeguards, many commenters urged OIG to include clinical laboratories as VBE participants. Several commenters noted that laboratories are increasingly providing precision diagnostic services and posited that this type of personalized medicine is the future of both preventive medicine and modern oncology care. Commenters expressed concern that making laboratories ineligible to be VBE participants may inhibit integration of these types of diagnostic services into practice. Others asserted that existing safeguards are sufficient to protect against any risk of fraud and abuse.

Commenters provided various examples of value-based arrangements involving laboratories. A commenter provided one example of a laboratory that entered into an arrangement with a payor under which it reviewed historical test results for a patient population to identify those likely to have a condition such as diabetes or chronic kidney disease so as to facilitate patients' enrollment in a disease management program.

Response: Under this final rule, laboratory companies may be VBE participants in a VBE and collaborate with other VBE participants without affecting the ability of other VBE participants to be eligible for safe harbor protection. However, laboratory companies are included on the list of carved out entities for which protection is not available under value-based safe harbors. As a result, any remuneration exchanged by a laboratory company will not be protected by a value-based safe harbor. We expressed our intent in the OIG Proposed Rule to make clinical laboratories ineligible for safe harbor protection because of heightened risk of fraud and abuse based on historical enforcement experience and because they are, like pharmaceutical companies and DMEPOS companies, heavily dependent on practitioner prescriptions and referrals. We were, and remain, concerned that these entities might misuse the value-based safe harbors as a means of offering remuneration primarily to market their products rather than as a means to create value for patients, providers, and payors by improving the coordination and management of patient care, reducing inefficiencies, or lowering costs. We also continue to believe that offering protection for remuneration exchanged by a laboratory company under the value-based safe harbors is unnecessary to effectuate the goals of the Regulatory Sprint because, as compared to other types of entities such as hospitals, physicians, and remote patient monitoring companies, laboratory companies are not on the front lines of care coordination.

We appreciate the input from commenters who pointed out various ways in which laboratories may be participating in care coordination. We are not persuaded that these examples warrant revisiting our policy. However, we want to be clear that nothing in this rulemaking is intended to discourage or prevent a laboratory from participating in care coordination arrangements such as those described by the commenters so long as the arrangements comply with the anti-kickback statute. A laboratory may look to other safe harbors, such as the personal services and management contracts safe harbor, as modified in this rule, to protect remuneration, and the advisory opinion process also remains available.

Comment: Several commenters requested that OIG clarify how clinical laboratories that are owned and operated by entities with other regulatory classifications, including hospitals, physician group, and medical device manufacturers, would be treated.

Response: We do not intend for the ineligibility of laboratory companies to extend to clinical laboratories that are owned and operated through other types of entities, such as hospitals and physician practices. Other types of entities, such as hospitals and physician practices, that operate clinical laboratories that are not the entity's predominant or core line of business are eligible to use the value-based safe harbors. This approach ensures that hospitals, physicians, and other entities with core care coordination roles are not precluded from using the safe harbors because they happen to provide some laboratory services, which we understand to be common in the industry. We also believe that this approach would preclude any suggestion that entities which have a predominant or core line of business other than a clinical laboratory (or other ineligible entity), such as a hospital, need to restructure their operations or corporate structure or otherwise need to modify the manner in which these entities operate.

In this final rule, we use the term ''laboratory companies'' to describe the intended category of ineligible entities, rather than the term ''clinical laboratory'' that was proposed, because the term ''laboratory company'' better describes the types of entities we intend to make ineligible to rely on the value-based safe harbors. We have long used the same terminology in the electronic health records safe harbor at paragraph 1001.952(y), and we intend for the term to have the same meaning here. Specifically, it describes independent companies that operate clinical laboratories and bill for the laboratory services they furnish through their own billing numbers. Thus, for example, if a hospital furnishes laboratory services through a laboratory that is a department of the hospital for Medicare purposes (including cost reporting) and the laboratory services are billed through the hospital's provider number, then the hospital would not be considered a laboratory company for purposes of determining eligibility to rely on a value-based safe harbor. In contrast, a hospital affiliated or hospital-owned laboratory company with its own supplier number that furnishes laboratory services that are billed using a billing number assigned to the company and not the hospital would not be eligible for safe harbor protection. This approach is consistent with the approach we describe in the discussion on entities with multiple business lines, below, in that it focuses on both the corporate structure and the predominant or core business function of an entity.

(d) Medical Device Manufacturers, Distributors, and Wholesalers

Comment: Many commenters encouraged OIG to allow medical device manufacturers, distributors, and wholesalers to be VBE participants, emphasizing, among other things, the role that these entities play in collecting, aggregating, analyzing, and sharing data to assist clinicians with care coordination and management. Others disagreed with our characterization of medical device manufacturers as not being on the front line of care coordination.

Another commenter asserted that our concerns that manufacturers may use value-based arrangements to tether clinicians or patients to a particular product are misplaced and disregard the improved cost and clinical outcomes that derive from standardizing the use of a superior product. Similarly, a commenter objected to the suggestion that manufacturers' participation in value-based arrangements is driven by marketing objectives. An integrated delivery system described existing value-based partnerships with medical device companies that it believes foster value by optimizing care pathways, improving patient experience, and sharing accountability for the results; according to this commenter, the medical device companies have been responsible, effective, and essential in providing high quality care at a low cost.

Response: We appreciate commenters' perspectives, and we recognize that manufacturers of devices and medical supplies may play an important role in some value-based arrangements, including by offering digital health technologies that can improve coordination and management of care. However, we continue to believe, as a general matter, that they are not as directly engaged in care coordination as other entities, such as providers and clinicians. We continue to have concerns, as described in the OIG Proposed Rule, based on our historical law enforcement experience, that manufacturers of devices and medical supplies could misuse the flexibilities afforded by the value-based safe harbors to offer kickbacks under the guise of care coordination activities or to tether a clinician to a particular product. Further, we believe there is a risk that these arrangements could result in providers selecting products that may not be clinically appropriate for, or in the best interest of, a patient. Based on our enforcement experience, these

concerns are heightened with respect to implantable devices used in a hospital or ambulatory surgical care setting, for which there is an elevated risk for patients undergoing implant surgery if devices are selected because of financial incentives rather than patients' best interests.

As discussed at section III.B.2.e.iii, we are adopting a pathway to protect the exchange of digital health technologies by manufacturers of devices and medical supplies under the care coordination arrangements safe harbor, which addresses some of the commenters' concerns. This pathway, which imposes an additional safeguard that applies only to manufacturers of devices and medical supplies and DMEPOS companies, balances our program integrity concerns with our interest in facilitating the deployment of health technologies for care coordination.

Comment: Many commenters encouraged OIG not to include device manufacturers, distributors, and wholesalers as VBE participants. Several of these commenters asserted that medical device manufacturers are not on the front line of care coordination. Another commenter asserted that, while larger companies may be well-positioned to engage in data-driven care coordination activities, most device manufacturers do not offer these types of services. The commenter was concerned that allowing medical device manufacturers to engage as VBE participants would unfairly advantage large manufacturers over smaller manufacturers, with larger companies using their size and scale to leverage their care coordination capabilities in a manner that disincentivizes purchasers from considering competing products. The commenter expressed concern that this dynamic may suppress medical innovation by smaller companies and encouraged OIG to consider a pilot program to assess potential impacts on smaller manufacturers.

Response: We appreciate the concerns raised by commenters, and, as we have explained, we share some of them. However, we also believe that digital health technologies hold great promise for improving coordination and management of care and achieving the goals of the Regulatory Sprint, and we believe that many of these promising technologies are either currently being developed, or will in the future be developed, by manufacturers of devices and medical supplies. We also believe that there will be instances where these digital health technologies are inextricably linked to a medical device. To that end, we are affording safe harbor protection to the exchange of digital health technologies by manufacturers of medical devices under the care coordination arrangements safe harbor.

With respect to the commenter's concerns about potential anticompetitive effects from allowing manufacturers of devices and medical supplies to participate, we are adopting a safeguard in the care coordination arrangements safe harbor that applies to manufacturers of devices and medical supplies, as limited technology participants, that prohibits exclusivity provisions and minimum purchase requirements. We designed this condition to prevent limited technology participants from locking-in use of their digital health technology, which may have beneficial effects for competition. For example, VBE participants may have increased opportunities to use multiple of types of digital health technology that best fits their needs.

In response to the commenter's concern about competition between large manufacturers and small manufacturers, nothing in this safe harbor is intended to favor large entities over small entities. We recognize that large manufacturers are likely to have additional resources to assess arrangements and determine whether they meet this safe harbor. We have strived to limit potential administrative burden as much as possible, while also including necessary safeguards against fraud and abuse. We believe that this safe harbor and the limited technology participant pathway will not require significant resources to ensure an arrangement meets all applicable conditions. Furthermore, use of these safe harbors and associated compliance is only one factor that may affect competition and innovation. There are several other factors that impact competition and innovation, but are not subject to the Federal anti-kickback statute and thus are outside the scope of this rulemaking.

Comment: With respect to adopting a definition for purposes of identifying the category of entities not eligible to be VBE participants, several commenters cautioned that it would be virtually impossible to define device manufacturers in a manner that would not preclude the types of digital health technologies that we stated we wished to include. Some commenters recommended that any definition that OIG adopts be limited to devices that are separately reimbursed by Medicare and not include companies that incorporate medical devices as part of their service offerings.

Many commenters encouraged us not to adopt a new definition, but instead to rely on existing definitions adopted by other divisions within the Department of Health and Human Services. However, a commenter asserted that OIG should not use CMS's definition of ''applicable manufacturer'' in 42 CFR 403.902, which relates to the Open Payments provisions of the Patient Protection and Affordable Care Act [17] (ACA), because that definition would not include manufacturers that do not have operations in the United States and reliance on this definition would be confusing because it includes manufacturers of durable medical equipment, which we proposed not to include in the definition of ''VBE participant.''

Response: Notwithstanding the changes to the definition of ''VBE participant,'' it remains necessary for us to adopt a definition of ''manufacturer of a device or medical supply'' to identify entities that are limited technology participants for purposes of the care coordination arrangements safe harbor.

The definition we are adopting at paragraph 1001.952(ee)(14)(iv) provides that ''manufacturer of a device or medical supply'' means an entity that meets the definition of applicable manufacturer in 42 CFR 403.902 because it is engaged in the production, preparation, propagation, compounding, or conversion of a device or medical supply that meets the definition of covered drug, device, biological, or medical supply in 42 CFR 403.902, but not including entities under common ownership with such entity. For purposes of this definition, we incorporate and adopt all of the related terminology in 42 CFR 403.902. We opted to rely on the ''applicable manufacturer'' terminology described in the Open Payments program and its implementing regulations because it effectively captures the universe of entities we designate as limited technology participants and those that will otherwise be carved out of safe harbor protection. Similarly, we opted to rely on this terminology because relying on an existing regulatory definition promotes consistency across the Department and minimizes additional potential regulatory burden. We are not adopting the alternative proposed definition that would include any entity that manufacturers any item that requires premarket approval by, or premarket notification to, the FDA, or that is classified by the FDA as a medical device because we believe the

[17] Public Law 111–148, 124 Stat. 119, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1029).

''applicable manufacturer'' terminology used in the Open Payments program provides a more fulsome definition that addresses not only the nature of the product (*i.e.,* whether it is regulated by the FDA as a device) but also the nature of the entity's functions vis a vis that product (*e.g.,* production, preparation, propagation, compounding, or conversion). We also intend to include medical device distributors or wholesalers on the list of ineligible entities because they are less likely to have a direct role in front line patient care coordination, and the ''applicable manufacturer'' definition at 42 CFR 403.902 includes distributors and wholesalers that hold title to the device or medical supply. Thus, it is a more comprehensive definition that aligns with our objectives. In order to capture distributors and wholesalers that do not hold title to the device or medical supply on the ineligible entity list, the ineligible entity list in each value-based safe harbor includes a separate category for ''a medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.''

With respect to the commenter who cautioned that reliance on the definitions from the Open Payments program would not include manufacturers that do not have operations in the United States, we refer the commenter to CMS regulations and guidance regarding how foreign companies can become subject to reporting obligations under section 1128G of the Act.

Comment: Many commenters shared our concerns regarding physician-owned distributorships and encouraged us to make them ineligible to be VBE participants. A commenter suggested that an entity that generates more than forty percent of its business from its physician owners should be not be eligible to be a VBE participant. Another commenter suggested that we require all VBE participants—regardless of whether or not they meet the definition of ''applicable manufacturer''—to meet the reporting obligations under section 1128G of the Act.

Response: We are adopting our proposed policy that physician-owned distributorships would not be eligible for safe harbor protection. Physician-owned distributors will be captured by one of two categories on the ineligible entity lists in each of the value-based safe harbors: Manufacturers of devices or medical supplies or medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies. As described above, the term ''manufacturer of devices or medical supplies'' is defined in paragraph 1001.952(ee).

As we stated in the OIG Proposed rule, physician-owned distributorships are inherently suspect under the anti-kickback statute because the financial incentives these companies offer their physician owners may induce physician owners to perform more procedures (or more extensive procedures) and to use the devices the physician-owned distributorships sell in lieu of other, potentially more clinically appropriate devices. Therefore, as described in greater detail below, physician-owned distributorships are also ineligible to rely on the care coordination arrangements safe harbor to protect digital health technology arrangements, even if they otherwise fit the definition of a manufacturer of a device or medical supply.

With respect to the commenter that suggested that we require all VBE participants to meet the reporting obligations under section 1128G of the Act, such a requirement is outside the scope of this rulemaking.

(e) DMEPOS Companies

Comment: Many commenters encouraged us to include DMEPOS companies in the definition of ''VBE participant.'' Commenters asserted that DMEPOS companies are on the front line of care coordination. Many commenters highlighted, for example, the role of DMEPOS companies in supporting care coordination through home infusion, home respiratory, and diabetes management services; others stated that DMEPOS companies engage directly with patients in a variety of ways, including visiting patients in their home. Commenters emphasized that DMEPOS companies are particularly critical in facilitating transitions from one care setting to another. Commenters also noted that the expansion of remote monitoring technologies has enhanced the role that DMEPOS companies play in care coordination and that device manufacturers are increasingly integrating digital technologies into medical devices that are classified as DMEPOS. With respect to these and other technologies, commenters noted that DMEPOS companies may provide useful data to support care coordination. Other commenters encouraged us to make DMEPOS companies ineligible for protection under the value-based safe harbors because they are not involved in front line patient care coordination. Others encouraged us to adopt additional safeguards specific to DMEPOS companies.

Response: We are persuaded by commenters that DMEPOS companies may have an important role in value-based arrangements, particularly in the context of post-acute care, and that they provide an array of health technology services, such as remote patient monitoring, that may facilitate the coordination and management of patient care. We believe that we must balance the role of these DMEPOS companies with our continued concerns, informed by our historical law enforcement experience, that some of these entities might misuse the protections afforded in the value-based safe harbors as a way to offer kickbacks under the guise of care coordination.

Given our stated interest in the deployment of digital health technologies to enhance coordination and management of care and consistent with the OIG Proposed Rule as explained elsewhere, we have defined the term limited technology participant to include manufacturers of medical supplies and entities or individuals that sell or rent DMEPOS. Limited technology participants, such as DMEPOS companies, may rely on the care coordination arrangements safe harbor to protect digital health technologies that they exchange with another VBE participant or the VBE, provided the arrangement satisfies an additional safe harbor condition that does not apply to other VBE participants, discussed in greater detail below. Our approach to DMEPOS in the final rule strikes a balance between encouraging the use of beneficial digital health technology, which may be offered by DMEPOS companies, for care coordination and protecting programs from potential fraud and abuse.

Comment: Some commenters asserted that DMEPOS companies would be willing to enter into risk-based arrangements and encouraged OIG to provide safe harbor protection for these types of arrangements.

Response: We believe the commenter is inquiring as to whether risk-based arrangements involving DMEPOS companies could satisfy the conditions of a value-based safe harbor. For the reasons described above and in the OIG Proposed Rule, DMEPOS companies are not eligible to rely on the value-based safe harbors, except under the limited technology participant pathway we have created in the care coordination arrangements safe harbor.

Comment: A commenter recommended that ''distribution vendors'' not be considered DMEPOS companies for purpose of any exclusion. The commenter argued that these vendors are needed to deploy digital medicine programs effectively by directly supporting patients through

home delivery of digital medical program items.

Response: All entities can be VBE participants under our revised approach, but entities that sell or rent covered DMEPOS are included in the ineligible entity lists in each value-based safe harbor and are thus ineligible to rely on those safe harbors, except under the limited technology participant pathway in the care coordination arrangements safe harbor. In the OIG Proposed Rule we listed manufacturer, distributor, or supplier of DMEPOS as an ineligible entity type. The final rule instead lists an entity or individual that sells or rents DMEPOS as ineligible for safe harbor protection (except that a limited technology participant is eligible under the care coordination arrangements safe harbor). The language in the final rule focuses on the nature of an entity's business—selling and renting DMEPOS—to better capture the higher risk entities that cannot use the safe harbors, and avoids potentially broad terms, such as ''supplier,'' that are defined elsewhere in Medicare regulations for different purposes. The language ''sells or rents'' is derived from a CMS definition of DMEPOS supplier.[18]

We removed the reference to DMEPOS manufacturers because entities that manufacture DMEPOS would fall under the final rule's definition of ''manufacturer of a device or medical supply,'' and it would have been duplicative to include these entities under both definitions. Some DMEPOS distributors will also be captured by the definition of ''manufacturer of a device or medical supply'' and would similarly be ineligible on that basis. We believe that the universe of entities that we intended to capture under the ''manufacturer, distributor, or supplier of DMEPOS'' terminology used in the OIG Proposed Rule will now be captured by one or both of the categories ''manufacturer of a device or medical supply'' and ''an entity that sells or rents [DMEPOS].''

Comment: Several commenters noted that many types of providers and entities, including physician practices, dentists, hospitals, and pharmacies, may be enrolled in the Medicare program as DMEPOS suppliers and questioned how an exclusion of DMEPOS companies, or requirements specific to DMEPOS companies, would apply to them. A commenter suggested that OIG should distinguish DMEPOS companies who derive only a small portion of their revenues from furnishing DMEPOS.

Response: In the final rule, the carve-out for DMEPOS companies in each of the value-based safe harbors does not apply to a pharmacy or to a physician, provider, or other entity that primarily furnishes services. In the OIG Proposed Rule, we sought comments on how to ensure that these types of entities would remain eligible for safe harbor protection even if they own or operate an entity that is ineligible, such as a DMEPOS company.[19] By specifically carving these entities out of the definition of DMEPOS companies, we ensure that these entities will not become ineligible for safe harbor protection. These entities and individuals are likewise not treated as ''limited technology participants.'' Thus, physicians, dentists, physician practices, and other providers (including, for example, hospitals), who primarily furnish services, as well as pharmacies, would not be considered DMEPOS companies for purposes of either the ineligible entities list or the ''limited technology participant'' definition. These parties are therefore able to rely on the three value-based safe harbors to the same extent as all other eligible VBE participants (including for arrangements involving digital health technologies), and they are not required to satisfy the additional condition that applies only to limited technology participants.

(f) Compounding Pharmacies

Comment: Several commenters responded to our solicitation of comments regarding the treatment of compounding pharmacies in the rule. Some commenters encouraged OIG not to distinguish between retail pharmacies, specialty pharmacies, and compounding pharmacies. One commenter expressed concern about generally offering protections to all compounding pharmacies, stating that ongoing vigilance for fraud and abuse is warranted for the compounding pharmacy industry. The commenter added that a more nuanced approach that screens for and offers protections in value-based arrangements for demonstrably good actors may further access to customized treatments, particularly for patients with rare diseases as well as pediatric patients. The commenter also described the risks of compounding without rigorous safety and quality practices. The commenter suggested that, to address quality, safety, and program integrity concerns with compounding pharmacies, OIG could limit participation to compounding pharmacies that exemplify good compounding practices through adherence to the U.S. Pharmacopeia (USP) Chapter 795 and attainment of Pharmacy Compounding Accreditation Board (PCAB) accreditation from the Accreditation Commission for Health Care (ACHC).

Other commenters believed that compounding is an essential part of patient care, including for specialty pharmacies such as infusion pharmacies that treat patients with severe conditions. Commenters suggested that pharmacists at compounding pharmacies may play a key role in helping coordinate individualized patient care. Commenters urged OIG to not exclude pharmacies from the proposed safe harbor based on the compounding services they provide. Some commenters raised concerns that excluding compounding pharmacies from the value-based safe harbors would expose the pharmacies to liability under the Federal anti-kickback statute for any remuneration they receive for providing prescription compounded medications or pharmacist-approved care services.

Some commenters explained their understanding that compounding is the preparation of a specific medication to meet the prescriber's exact specifications and to be dispensed directly to an individual patient, pursuant to a valid prescription for that patient. Such drugs are prescribed when commercially available products do not meet patient needs. Commenters noted that compounding should not be confused with manufacturing or the mass production of drug products, nor should it be confused with making copies of commercially available drug products, which is not allowed by law under section 503A(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a(b)(1)(D)).

Response: We agree that pharmacists, including pharmacists at compounding pharmacies, can play important roles in coordinating and managing patient care and as members of care teams, including for patients with rare and serious conditions. Under the final rule, all pharmacies and pharmacists can participate in VBEs. As explained further below, most pharmacies and pharmacists will be eligible to rely on the value-based safe harbors to protect remuneration, even if the pharmacy engages in some compounding of drugs.

However, under the final rule, for reasons explained below, pharmacies that primarily compound drugs or primarily dispense compounded drugs are ineligible to protect remuneration under the value-based safe harbors, as well as the safe harbor protections for patient engagement tools and supports

[18] 42 CFR 424.57(a).

[19] 84 FR 55706 (Oct. 17, 2019).

(paragraph 1001.952(hh)) and outcomes-based payments (amended paragraph 1001.952(d)). When we refer to compounded drugs in this rule, we refer to the common industry understanding of them as drugs that are specifically combined, mixed, or altered and prepared for individual patients, or that purport to be such drugs. As noted by the commenters, compounded drugs are often prescribed or dispensed for patients for whom commercially available products are not clinically suitable.[20] We are not defining ''compounding'' or ''compounded drugs'' in regulatory text in this rule. For purposes of this rule, compounding pharmacies include entities that primarily compound drugs or primarily dispense compounded drugs, such as topical pain creams, with or without licensure or valid prescriptions. Accordingly, we are not adopting the narrower definitional suggestions made by commenters.

We explained in the OIG Proposed Rule that we were considering whether specific types of pharmacies, such as compounding pharmacies, should be carved out of safe harbor protection even if others, such as retail and community pharmacies, are eligible for safe harbor protection. The OIG Proposed Rule states that pharmacies that specialize in compounding pharmaceuticals may pose a heightened risk of fraud and abuse, as evidenced by our enforcement experience, and may not play a direct role in patient care coordination.[21] We remain deeply concerned about fraud and abuse in the compounding pharmacy industry.

Our recent criminal, civil, and administrative enforcement history shows an increasing number of fraud allegations, investigations, and cases related to compounded drugs, including topical compounded drugs such as creams, gels, and ointments to relieve pain.[22] OIG's oversight experience also has found that Medicare Part D spending for compounded topical drugs was 24 times higher in 2016 than it was in 2010, which raises concerns about fraud and abuse.[23] According to the FDA, there are also safety and effectiveness concerns related to compounded drugs, which are not FDA approved.[24] This is also an area of significant growth in Medicare Part D spending; spending for compounded topical drugs was 24 times higher in 2016 than it was in 2010, some of which may be attributed to suspect billing practices. In 2016, OIG found that about 550 pharmacies had engaged in questionable Part D billing practices for compounded topical drugs and warranted further scrutiny. Each pharmacy billed extremely high amounts for at least one of five measures that OIG has developed as indicators of possible fraud, waste, and abuse.[25] In light of this enforcement and oversight experience, we conclude that the risks of allowing pharmacies that primarily compound drugs or primarily dispense compounded drugs to rely on the value-based arrangements, patient engagement tools and supports, and outcomes-based payments safe harbors outweigh the potential benefits. As explained further below, other pharmacies are eligible to rely on the safe harbors. As with other entities ineligible for protection under the value-based, patient engagement tools and supports, and outcomes-based payments safe harbors, compounding pharmacies can still be VBE participants.

We recognize that many pharmacies may dispense some compounded drugs. For purposes of this rule, a pharmacy is only considered to be a compounding pharmacy (and ineligible for protection under certain safe harbors) if it primarily compounds drugs or primarily dispenses compounded drugs. We anticipate that most retail pharmacies and community pharmacies that offer care coordination and management services will not be covered by this category and will be eligible to rely on the safe harbors.

We are not adopting the commenters' suggestions to provide safe harbor protection for remuneration exchanged by compounding pharmacies that demonstrate that they are good actors or that exemplify good compounding practices through adherence to USP Chapter 795 and attainment of PCAB accreditation from ACHC. We believe the suggested approaches would introduce additional complexity and uncertainty into the safe harbors by further attempting to distinguish among different types of compounding pharmacies.

We do not prescribe a specific standard or test for assessing whether a pharmacy primarily compounds drugs or primarily dispenses compounded drugs. Entities may use a variety of different methodologies, depending on their circumstances. We expect parties to use a reasonable methodology, which they may wish to document. If an entity has multiple lines of business, with one line of business being a compounding pharmacy, the entity should use the multiple lines of business test as laid out in section III.B.2.e.v of this preamble to determine whether it is eligible to rely on the safe harbors or a compounding pharmacy ineligible to rely on the safe harbors.

Entities seeking safe harbor protection that are uncertain as to whether they are eligible to rely on the value-based safe harbors or any other safe harbor for a particular arrangement may wish to use the OIG advisory opinion process.

Finally, we want to clarify that nothing in this rulemaking should affect patients' access to medically necessary compounded drugs. The dispensing of compounded drugs pursuant to applicable coverage and billing rules does not implicate the Federal anti-kickback statute. Nor does this rule speak to the pricing of such products. With respect to remuneration paid to compounding pharmacies or pharmacists for services furnished to patients, whether such payments implicate the statute is a case-by-case determination and the safe harbors for employment and personal services and management contracts remain available. As noted elsewhere, with respect to value-based contracting with pharmaceutical manufacturers, we may consider safe harbor protection for such arrangements in future rulemaking.

iii. Digital Health Technologies and Limited Technology Participants

As explained in more detail below, the final rule includes a pathway for protection of ''digital health technology'' arrangements involving ''limited technology participants,'' as those terms are defined under the care coordination arrangements safe harbor.

[20] *See, e.g.,* FDA, Compounding and the FDA: Questions and Answers, *available at https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers* (addressing what is compounding and why some patients need compounded drugs).

[21] 84 FR 55704 (Oct. 17, 2019).

[22] *See, e.g.,* Press Release, U.S. Department of Justice, Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay $21.36 Million to Resolve False Claims Act Allegations (Sept. 18, 2019), *https://www.justice.gov/opa/pr/compounding-pharmacy-two-its-executives-and-private-equity-firm-agree-pay-2136-million;* Press Release, U.S. Department of Justice, Four Florida Men Charged for Their Roles in a $54 Million Compound Pharmacy Kickback Scheme (June 5, 2020), *https://www.justice.gov/opa/pr/four-florida-men-charged-their-roles-54-million-compound-pharmacy-kickback-scheme;* OIG, Civil Monetary Penalties and Affirmative Exclusions, Texas Company and Owner Agree to Voluntary Exclusion (July 20, 2020).

[23] OIG, Questionable Billing for Compounded Topical Drugs in Medicare Part D (Aug. 2018), *available at https://oig.hhs.gov/oei/reports/oei-02-16-00440.asp.*

[24] FDA, Compounding and the FDA: Questions and Answers, *available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm.*

[25] OIG, Questionable Billing for Compounded Topical Drugs in Medicare Part D (Aug. 2018), *available at https://oig.hhs.gov/oei/reports/oei-02-16-00440.asp.*

This pathway responds to comments supporting protection of digital technology arrangements involving medical device manufacturers and DMEPOS companies. VBE participants that are not on the ineligible entity list may exchange digital health technologies (and any other technologies) under the care coordination arrangements safe harbor, and they are not subject to the additional safe harbor condition that applies to limited technology participants. Further, the pathway for limited technology participants does not apply to the substantial downside risk and full financial risk safe harbors. The care coordination arrangements safe harbor is available for digital health technology arrangements between limited technology participants and VBE participants in risk-based arrangements.

For purposes of the pathway for limited technology participants, we are defining the term ''limited technology participant'' at paragraph 1001.952(ee)(14)(iii) to mean a VBE participant that exchanges digital health technology with another VBE participant or a VBE and that is: (A) A manufacturer of a device or medical supply, but not including a manufacturer of a device or medical supply that was obligated under 42 CFR 403.906 to report one or more ownership or investment interests held by a physician or an immediate family member during the preceding calendar year, or that reasonably anticipates that it will be obligated to report one or more ownership or investment interests held by a physician or an immediate family member during the present calendar year (for purposes of this paragraph, the terms ''ownership or investment interest,'' ''physician,'' and ''immediate family member'' have the same meaning as set forth in 42 CFR 403.902); or (B) an entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services). In short, many manufacturers of medical devices and supplies (but not physician-owned distributors) and DMEPOS companies are eligible to be limited technology participants if they fit in this definition.

We are defining ''digital health technology'' at paragraph 1001.952(ee)(14)(ii) broadly to mean hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care; such term includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose. Importantly, this definition specifies the types of technology a limited technology participant can exchange under the safe harbor. It does not constrain the types of technology that can be exchanged by other VBE participants eligible to use the safe harbor.

Comment: Several commenters emphasized the importance of allowing health technology companies to participate as VBE participants and asserted that making medical device manufacturers ineligible to be VBE participants may impact the availability of digital technologies for purposes of coordinating and managing care because no meaningful line can be drawn between medical device companies and health technology companies. For example, a commenter explained that they offer both traditional medical devices and other digital health technologies, the latter of which includes clinical decision support tools and artificial intelligence-assisted diagnostic support tools. Another commenter noted that manufacturers of implantable devices often pair their products with software solutions to support patient diagnosis and treatment. A trade association representing device manufacturers described a program where a manufacturer of automated external defibrillators and cardiac monitoring devices with transmitting capabilities offers a device-agnostic software solution that permits coordination between EMS providers and hospitals. According to the commenter, the software enables receiving hospitals to access cardiac data in real time so they can have advance notice of patients en route and provide consultation back to EMS personnel to direct the patient to the appropriate treatment location (*e.g.,* community hospital, hospital with specialized services). Another commenter explained how digital health technology is integrated with medical devices used by patients to provide data to patients and providers for patient engagement and treatment adherence purposes. Other commenters emphasized the difficulty of clearly distinguishing between device manufacturers and digital health technology companies, and that both may provide a mix of traditional medical devices and digital health technology. Commenters supported an approach that would not unintentionally exclude beneficial digital health technology from protection under the safe harbor.

Response: In the OIG Proposed Rule, we expressed interest in protecting remuneration in the form of a wide range of mobile and digital technologies for the coordination and management of patient care, including, by way of example, remote monitoring, predictive analytics, data analytics, care consultations, patient portals, telehealth and other communications, and software and applications that support services to coordinate and monitor patient care and health outcomes (for individuals and populations). We noted diabetes management services that leverage devices and cloud storage services to monitor blood sugar levels and transmit data as an example.

While recognizing the promise that digital health technologies have for improving care coordination and health outcomes, in the OIG Proposed Rule we also raised fraud and abuse concerns associated with medical device manufacturers based on our historical law enforcement experience. Section III.B.2.e.d. explains those concerns in more detail. Recognizing these factors, we solicited comments generally on how best to protect beneficial digital technologies and mitigate fraud and abuse risks. This included requesting comment on definitions and factors to consider for specific types of entities that would protect digital technology and not be too narrow or broad.

Consistent with this request for comments, the intent in the OIG Proposed Rule, and to address comments received, we define the term ''digital health technology'' at paragraph 1001.952(ee)(14)(ii) and we define ''limited technology participant'' at paragraph 1001.952(ee)(14)(iii). These definitions balance the interests we raised in the OIG Proposed Rule by protecting beneficial digital health technology and mitigating the fraud and abuse risks by specifying the types of technology that limited technology participants can furnish under the care coordination arrangements safe harbor. This approach also addresses concerns raised by commenters regarding unintentionally excluding beneficial digital health technology from safe harbor protection. We discuss each definition in more detail below in this section.

Digital health technology is defined as hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care; such term includes any internet or other connectivity service that is necessary and used to

enable the operation of the item or service for that purpose. We intend for this term to encompass a wide range of digital health technologies, including technologies that are not yet developed or available. It also includes associated internet or other connectivity services, including dial-up, that are necessary and used to enable the operation of the item or service for the purpose of coordinating and managing care. The term ''digital health technology'' includes, for example, the software solution described by the commenter that enables hospitals to access data from cardiac devices used by EMS providers in the field so that they can coordinate and manage the care of patients undergoing a cardiac emergency, including connectivity services, such as mobile hotspots and plans, necessary to enable the EMS providers to transmit data from the field to the hospital.

Only limited technology participants are limited to the types of technology set out in the definition of ''digital health technology.'' Other VBE participants eligible for the safe harbor may provide additional types of technology so long as the value-based arrangement squarely meets all safe harbor conditions.

We share commenters' views regarding the desirability of enabling VBE and VBE participants to leverage digital health tools to support the coordination and management of care. All individuals (except for patients) and entities are eligible to be VBE Participants, and this includes health technology companies, including those that are not traditionally involved in health care or may be new entrants to health care. Except as otherwise provided in the safe harbor regulations, health technology companies are eligible to rely on the protection of the safe harbors for value-based arrangements with other VBE participants, provided that their arrangements squarely meet all applicable safe harbor conditions.

The question arose in the OIG Proposed Rule, and remains relevant here, whether manufacturers of devices and medical supplies and DMEPOS companies are health technology companies. For most purposes, as described above, these entities are carved out of the value-based safe harbors and are ineligible to rely on them. However, we are creating a pathway to enable these entities to deploy digital health technologies under the care coordination arrangements safe harbor at paragraph 1001.952(ee). For purposes of this safe harbor, manufacturers of devices or medical supplies (as defined in paragraph 1001.952(ee)) and DMEPOS companies (*i.e.,* entities or individuals that sell or rent covered DMEPOS, not including physicians or providers that primarily furnish services and pharmacies) that exchange digital health technologies with another VBE participant or the VBE are collectively termed ''limited technology participants'' in paragraph 1001.952(ee).

Limited technology participants may use the care coordination arrangements safe harbor to protect the exchange of digital health technologies with other VBE participants or the VBE if the arrangement meets an additional safe harbor condition, described below. Limited technology participants may not, by definition, rely on the care coordination arrangements safe harbor to exchange other forms of remuneration. All other entities eligible to use the safe harbor can also exchange remuneration in the form of digital health technology, and they do not have to meet the additional safe harbor conditions that apply only to limited technology participants at paragraph 1001.952(ee)(8). For example, physicians and providers that primarily furnish services are not treated as limited technology participants and are therefore not obligated to meet the additional conditions that apply to limited technology participants.

In short, remuneration in the form of digital health technology may be exchanged under the care coordination arrangements safe harbor by all entities that are not carved out of the safe harbor, as well as limited technology participants.

Consistent with our statements in the OIG Proposed Rule reflecting our intent that physician-owned distributorships not be eligible to rely on the value-based safe harbors, we do not intend for physician-owned distributorships to be able to use the limited technology participant pathway in the care coordination arrangements safe harbor. To foreclose this possibility, we clarify in paragraph 1001.952(ee)(14) that the term ''limited technology participant'' does not include manufacturers of devices or medical supplies that were obligated under 42 CFR 403.906 to report one or more ownership or investment interests held by a physician or an immediate family member during the preceding calendar year, or that reasonably anticipate that they will be obligated to report one or more ownership or investment interests held by a physician or an immediate family member during the present calendar year. For purposes of this definition, the term ''manufacturer of a device or medical supply'' has the meaning set forth in paragraph 1001.952(ee)(14), and the terms ''ownership or investment interest,'' ''physician,'' and ''immediate family member'' have the meaning set forth in 42 CFR 403.902. We take this opportunity to make clear that this regulatory provision should not be construed as an official definition of unlawful physician-owned distributorships or physician-owned entities more broadly. This regulation does not alter our long-standing guidance regarding physician-owned distributorships, and we specifically reaffirm the guidance in our 2013 Special Fraud Alert on Physician-Owned Entities.[26]

iv. Pharmacies Other Than Compounding Pharmacies

Comment: The overwhelming majority of commenters on this topic supported allowing pharmacies to be VBE participants. Commenters cited a wide range of reasons, including that pharmacies and pharmacists are already involved in many aspects of care coordination and management and that they are on the front line of care coordination because they often serve as the key point of contact between patients and the health care system due to their geographic proximity to patients. Commenters emphasized that pharmacies provide many services to patients, not just items. A commenter also noted that an ACO may be a VBE and that a number of ACOs currently integrate pharmacists for medication management and other services. Conversely, another commenter suggested that pharmacies should not be eligible because they present many of the same concerns as pharmaceutical manufacturers, wholesalers, and distributors.

Response: With the exception of compounding pharmacies (as explained in section III.2.e.ii.f of this preamble), pharmacies can utilize each of the final value-based safe harbors for value-based arrangements and are not subject to any pharmacy-specific restrictions or limitations. Pharmacies other than compounding pharmacies also are eligible for safe harbor protection under the safe harbors for patient engagement tools and supports (paragraph 1001.952(hh)) and outcomes-based payments (amended paragraph 1001.952(d)). We are persuaded that many pharmacies and pharmacists have the potential to facilitate coordination and management of care for patients and

[26] *See* OIG, Special Fraud Alert: Physician-Owned Entities (Mar. 26, 2013), *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf.*

that their participation in value-based arrangements may further the purposes of this final rulemaking. Except in the case of compounding pharmacies, these potential benefits outweigh our program integrity concerns, which are adequately addressed by the requirements of the value-based safe harbors.

v. Entities With Multiple Business Lines

Comment: We received several comments seeking guidance on how entities with multiple business lines or with multiple regulatory classifications would be viewed for purposes of safe harbor eligibility. Some commenters requested clarification on how the eligibility standards would be impacted by corporate affiliations or shared ownership. Another commenter noted that some health systems are involved in device and technology development.

Some questioned how OIG would view an entity that operates both eligible and ineligible business lines through separate business units, with certain commenters suggesting that it would be impossible to distinguish between types of entities because the health care industry is not siloed in this manner. Others asserted that the fact that many companies have multiple business lines is reason enough for OIG not to make any types of business lines ineligible to be VBE participants. Another commenter requested that clinical quality improvement and data registries be eligible to be VBE participants, regardless of their ownership or other status.

Response: Under the final rule, the question of whether a particular entity is eligible to rely on a safe harbor, or whether an entity fits the definition of a limited technology participant, is assessed at the corporate entity level by considering the corporate entity's predominant or core line of business. We did not propose, and we are not finalizing, standards relating to common ownership or corporate affiliation. Corporate affiliation, whether by majority ownership, common ownership, or another structure, has no bearing on eligibility.

For example, a pharmacy (other than a compounding pharmacy as explained in section III.2.e.ii.f) that is under common ownership with a PBM would be eligible to rely on the value-based safe harbors, notwithstanding the fact that the pharmacy is related to a PBM, which is ineligible to rely on those safe harbors. Likewise, within a health system that is comprised of multiple corporate entities, the fact that one or more of those entities might engage in activities that make it a manufacturer of devices or medical supplies would not impact the availability of the safe harbor to other corporate entities in the health system that do not engage in such activities.

Where a single corporate entity operates multiple business lines, eligibility turns on the entity's predominant or core business. For example, a pharmacy that is operated within the same corporate entity as a pharmaceutical manufacturer would not be eligible to rely on these safe harbors to the extent the corporate entity's core function is the manufacturing of pharmaceuticals and the pharmacy operation merely supports the manufacturing line of business. Similarly, where a single corporate entity manufactures both pharmaceuticals and medical devices, the question of eligibility would focus on which line of business is the predominant or core line of business of that corporate entity. For example, if a corporation's predominant function is the manufacturing of devices (including, for example, preparation, propagation, assembly, and processing of devices) and it also manufactures a pharmaceutical product that is incorporated into and integral to a medical device (for example, a drug-eluting medical device), the entity would be treated as a manufacturer of devices or medical supplies because that remains its core business and function. The question of whether a quality improvement or data registry will be eligible will similarly turn on whether it is housed within a corporate entity whose predominant function places it on the carve-out list.

Large corporations that are organized with multiple business lines within a single corporate entity will need to assess whether they have a predominant or core business. We do not prescribe a specific standard or test for assessing an entity's predominant or core business function, and we expect that entities may use a variety of different methodologies, depending on their circumstances. We would expect parties to use a reasonable methodology, which they may wish to document. For example, share of revenues may be a relevant metric for some entities, but for others where one or more products are still in development, revenues may not be an appropriate metric. Entities seeking safe harbor protection that are uncertain as to whether they are eligible to rely on the value-based safe harbors for a particular arrangement may wish to use the OIG advisory opinion process.

Parties seeking protection under the safe harbors may first need to assess the regulatory text for ineligible entities in the specific safe harbor of interest. For example, where an entity's business includes the sale or rental of DMEPOS covered by a Federal health care program, the question of eligibility is addressed by the regulatory text, which specifies that the ineligibility of DMEPOS companies does not apply to a pharmacy or a physician, provider, or other entity that primarily furnishes services. Thus, for example, a disease management company that primarily furnishes a suite of disease management services (*e.g.,* wellness coaching, patient education, health technology tools to promote medication adherence) and also sells or rents DMEPOS in support of these services would be eligible to rely on the value-based safe harbors and would not be subject to the constraints imposed on limited technology participants. Conversely, an entity that sells or rents covered DMEPOS and does not primarily furnish services would be ineligible, except as a potential limited technology participant under the care coordination arrangements safe harbor.

We also note that, wholly apart from any value-based arrangement, transfers of remuneration from one entity to another may implicate the Federal anti-kickback statute if those transfers of remuneration are intended to induce or reward referrals for items and services covered by a Federal health care program. This potential liability arises even where the recipient subsequently uses the remuneration in a manner that is protected by a safe harbor. Thus, for example, if an ineligible entity transferred remuneration to a VBE participant in order for the recipient VBE participant to induce or reward referrals back to the ineligible entity, the initial transfer may result in liability under the Federal anti-kickback statute, even if the recipient VBE participant's subsequent transfer of the remuneration to other VBE participants or to patients is protected under a safe harbor.

Comment: Several commenters noted that many providers, including hospitals and health systems, often own or operate pharmacies and questioned how an exclusion of pharmacies would apply to them.

Response: Other than pharmacies that primarily compound drugs or primarily dispense compounded drugs, pharmacies are not subject to any limitations or restrictions under this final rule, and thus ownership or operation of many pharmacies by another provider would have no impact on eligibility. Should a compounding pharmacy exist within a health system that is comprised of multiple corporate entities, the fact that one of the entities may be a pharmacy that primarily compounds drugs or primarily

dispenses compounded drugs would not impact the availability of the safe harbor to other corporate entities in the health system. Moreover, should a compounding pharmacy exist within a single entity that also furnishes other services, such as health clinic that furnishes physician services, the entity would apply the multiple lines of business test to determine whether or not the entity would be characterized as a compounding pharmacy.

Comment: Some commenters described companies that are regulated as both CLIA laboratories and manufacturers of devices or medical supplies because they perform their own FDA-regulated in-vitro diagnostic tests at their own CLIA-certified laboratories and sought clarification regarding how they would be viewed.

Response: We have replaced the term ''clinical laboratory'' with the term ''laboratory company'' in this final rule to clarify the type of entities that we intend to make ineligible to rely on the value-based safe harbors. The term ''laboratory company'' refers to independent companies that operate clinical laboratories and bill for the laboratory services they furnish through their own billing numbers. Consistent with the approach described above, the entity would need to consider what its predominant or core business function is—manufacturing (*e.g.,* preparation, propagation, assembly, processing) a medical device or furnishing laboratory services. Without further details regarding the commenters' specific business operations, we are unable to provide a precise response here.

Comment: A commenter noted that a pharmacy is included as a ''laboratory'' under CLIA. Other commenters noted that pharmacies may be co-located with health clinics or owned and operated by other types of providers. The commenters sought guidance on how these relationships between entity types would impact eligibility for protection under the safe harbors.

Response: As discussed above, and based upon the comments, we have revised the terminology in this final rule to refer to laboratory companies rather than clinical laboratories, and we intend for ''laboratory companies'' to mean independent companies that operate clinical laboratories and bill for the laboratory services they furnish through their own billing numbers. Consistent with the approach set forth above, because a pharmacy's predominant or core business function is to provide pharmacy services, not laboratory services, we would not consider the fact that pharmacies are treated as laboratories for other regulatory purposes to impact their eligibility to rely on the value-based safe harbors. As noted previously, pharmacies that primarily compound drugs or primarily dispense compounded drugs would not be eligible for safe harbor protection.

vi. New Safe Harbor Conditions

Comment: With respect to potential additional safeguards for VBE participants generally, commenters suggested a wide range of options, some of which we stated that we were considering in the OIG Proposed Rule (*e.g.,* prohibitions on exclusivity, required data reporting or monitoring). Some commenters also recommended that we implement these additional safeguards for certain types of entities (*e.g.,* medical device manufacturers).

Response: Consistent with the proposal within the OIG Proposed Rule, we are adopting an additional safeguard in the care coordination arrangements safe harbor targeted to manufacturers of devices and medical supplies and DMEPOS companies that exchange digital health technologies to mitigate the increased risk of abuse presented by allowing these entities to use this safe harbor.

As discussed above, we have created a new category of VBE participants, ''limited technology participants,'' which is comprised of manufacturers of devices and medical supplies and DMEPOS companies that exchange digital health technology with another VBE participant or the VBE. Consistent with our proposal in the OIG Proposed Rule, we are adopting a requirement in the care coordination arrangements safe harbor that the exchange of digital health technologies by limited technology participants may not be conditioned on any recipient's exclusive use, or minimum purchase, of any item or service manufactured, distributed, or sold by the limited technology participant. This additional safeguard addresses the specific program integrity concerns presented by manufacturers of devices and medical supplies and DMEPOS companies, which are heavily dependent on practitioner referrals and who might use value-based arrangements to tether clinicians to their products or to secure guaranteed referral streams.

Comment: Some commenters suggested that applying safeguards to specific types of entities, and not others, might deter those entities from participating in value-based arrangements.

Response: First, we note that we have not imposed any additional conditions on specific types of entities in the substantial downside financial risk safe harbor or the full financial risk safe harbor. Second, we do not concur with the commenter's assertion that the limited technology participant pathway will disincentivize participation in value-based arrangements; this framework allows manufacturers of devices and medical supplies and DMEPOS companies to participate in value-based arrangements involving digital health technology and benefit from protection under the care coordination arrangements safe harbor if they satisfy all safe harbor conditions.

Comment: In response to our proposal to include a safeguard that prohibits exclusivity provisions, many commenters expressed support for such a safeguard. Others cautioned that exclusivity provisions in contractual arrangements can be appropriate in certain situations, such as where substantial financial investments are required or where exclusivity is consistent with intellectual property rights and protections. Some commenters encouraged us to investigate the pros and cons of prohibiting exclusivity provisions before adopting this safeguard. At least two commenters opposed any potential prohibition of exclusivity requirements. One commenter asserted that no manufacturer has the capability or resources to ensure that all of its value-based arrangement offerings always operate as a ''plug and play,'' always interchangeable, product agnostic system. Another commenter stated that parties to value-based arrangements should have flexibility to require use of a medical device where clinical evidence dictates that a particular practice not currently in use would vastly improve outcomes.

Response: We are adopting our proposal to preclude protection for the exchange of remuneration conditioned on a recipient's exclusive use, or minimum purchase, of any item or service manufactured, distributed, or sold by a limited technology participant in the care coordination arrangements safe harbor. We are only applying this condition to remuneration exchanged by limited technology participants; it does not apply to any other VBE participants. We are only adopting this condition in the care coordination arrangements safe harbor, not the other value-based safe harbors. We recognize that exclusivity provisions may be appropriate business terms in certain contexts. However, precluding safe harbor protection for arrangements that include exclusivity provisions tied to products offered by limited technology participants is an important safeguard. This safeguard mitigates risk that these entities, which

are heavily dependent on practitioner referrals to sell their products, will attempt to use the care coordination arrangements safe harbor to protect arrangements intended to generate product sales or arrangements that lock practitioners and patients into using products that may not be in the patients' best interests in the clinical judgment of the practitioners.

The safe harbor requirement that remuneration exchanged by limited technology participants may not be conditioned on any recipient's exclusive use or minimum purchase of the limited technology participant's products does not prevent use of products based on clinical best evidence. Nor does it prevent requirements in value-based arrangements that providers use products based on clinical evidence showing improved outcomes, when those products are in a patient's best interests in the judgment of their practitioners. Nor does the provision require that all value-based arrangements be product-agnostic or that the digital technology provided under such an arrangement be fully interchangeable with other products. The provision does mean that, where remuneration is exchanged by a limited technology participant, the VBE participants will not be entitled to safe harbor protection under the care coordination arrangements safe harbor if the limited technology participant conditions the remuneration on the exclusive use of its product or a minimum purchase amount. This safe harbor requirement does not apply to remuneration exchanged by VBE participants that are not limited technology participants.

f. Value-Based Purpose

Summary of OIG Proposed Rule: We proposed to define a ''value-based purpose'' as: (i) Coordinating and managing the care of a target patient population; (ii) improving the quality of care for a target patient population; (iii) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (iv) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Summary of Final Rule: We are finalizing, without modification, our definition of ''value-based purpose.''

Comment: While several commenters expressed support for our proposed definition of ''value-based purpose'' as drafted, the majority of commenters sought clarification on the term. For example, commenters sought clarification on how quality would be defined and measured under the value-based purpose and, more specifically, whether certain measures would be seen as reducing quality. Another commenter requested that OIG address how parties to a value-based arrangement would need to document that the arrangement met a value-based purpose. Other commenters sought confirmation that the definition of ''value-based purpose'' does not require parties to succeed in achieving the applicable purpose.

Response: As a threshold matter, the definition of ''value-based purpose'' was crafted to provide parties with flexibility to develop innovative care arrangements and strategies specific to the needs of their target patient populations. We are not prescribing how parties define and measure quality to qualify for the definition or how parties document the ways in which they intend to achieve the VBE's value-based purpose(s). Whether certain measures reduce quality is a fact-specific inquiry. Further, neither the definition of ''value-based purpose'' nor the value-based safe harbors requires parties to achieve the VBE's value-based purpose(s); rather, the definition of ''value-based purpose'' should be read in conjunction with the definition of ''value-based activity,'' which requires value-based activities to be reasonably designed to achieve the VBE's value-based purpose(s). Documentation requirements are specified in individual safe harbors.

Comment: Multiple commenters requested further guidance on the fourth value-based purpose of transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Response: We are finalizing the fourth value-based purpose in recognition that parties transitioning to value-based care may need to provide infrastructure and perform other activities necessary to transition to the assumption of downside financial risk. For example, as discussed in section III.B.5 below, parties to value-based arrangements that meet the requirements of the full financial risk safe harbor may exchange remuneration during a twelve-month phase-in period, where the VBE is contractually obligated to assume full financial risk in the next 12 months but has not yet assumed such risk. During this phase-in period, the parties may have, as a value-based purpose, the purpose of transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population, and the parties may exchange, among other things, remuneration necessary to enable the VBE to transition to the assumption of full financial risk.

Comment: Other commenters advocated for revisions to the definition of ''value-based purpose.'' These comments generally focused on two issues related to the value-based purpose of appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population: Whether the definition of ''value-based purpose'' should protect: (i) Cost-reduction efforts more broadly, rather than only to the benefit of payors; and (ii) cost-reduction efforts only when paired with improved quality or maintenance of already-improved quality of care.

With respect to the first issue, commenters generally were in favor of expanding the third purpose to cover all cost-reduction efforts, not just those that benefit payors. At least two commenters asserted that this expansion would be necessary to protect gainsharing arrangements.

Commenters' opinions varied on the second issue, related to our proposal that reducing costs to, or the growth in expenditures of, payors must be accomplished without reducing the quality of care for the target patient population, with some expressing support and others opposition. Many commenters opined on our alternative proposal to include the reduction of costs to, or growth in expenditures of, payors in the definition of ''value-based purpose'' only where there is also an improvement in patient quality of care or the parties are maintaining an improved level of care. On the one hand, certain commenters believed this alternative standard would be overly prescriptive and difficult to measure; others expressed support, with one stating that a reduction in costs alone is not true value and that the improvement of care should be the first priority.

Response: We are finalizing this portion of the definition, as proposed. A goal of this rulemaking is to support quality improvements and cost efficiencies achieved through better care coordination that benefit patients and the health care delivery system. In our view, arrangements that do not result in a reduction in costs to, or growth in expenditures of, payors—such as reductions in surgical suite costs for a

hospital—do not further this goal sufficiently to warrant protection under the third value-based purpose definition. The definition of ''value-based purpose'' that we are finalizing is not intended to foreclose internal-cost savings arrangements, such as gainsharing, in their entirety; however, parties must consider whether such arrangements would further other purposes in the ''value-based purpose'' definition and the conditions of the applicable value-based safe harbor. We also do not believe a higher standard of improving or maintaining already improved quality of care is necessary. We are persuaded that preventing reductions in quality of care, paired with the safeguards in each of the value-based safe harbors, provides both flexibility and sufficient protection against the potential for patient harm.

Comment: A commenter asserted that VBEs should have at least one value-based purpose related to patient care improvement and expressed concern that allowing VBEs to focus solely on cost reduction would compromise patient care and have a disproportionate impact on patients with rare conditions.

Response: While a VBE or value-based arrangement may, but is not required to, have as a value-based purpose improving the quality of care for a target patient population, none of the value-based purposes protect value-based arrangements that compromise patient quality of care. Of the two value-based purposes that incorporate cost control or cost reduction concepts, one requires the *appropriate* reduction in costs to, or growth in expenditures of, payors *without reducing the quality of care* for a target patient population; the other requires the transition of health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the *quality of care and* control of costs of care to payors for a target patient population. Both of these value-based purposes emphasize the importance of ensuring patient quality of care.

We further highlight that each of the value-based safe harbors includes a safeguard precluding safe harbor protection for value-based arrangements that stint on medically necessary patient care; this safeguard provides that the value-based arrangement may not induce parties to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient.

Comment: A commenter expressed concern that the ''value-based purpose'' definition may lead to patient harm, fails to protect adequately against abusive cycling of patients for financial gain, and potentially impinges on the professional judgment of health care professionals.

Response: We share the commenter's concerns about patient harm, abusive cycling of patients for financial gain and compromised professional judgment. We have addressed these concerns through various safeguards and requirements of the value-based safe harbors and the patient engagement and support safe harbor. We note that compliance with the value-based purpose definition does not necessarily qualify parties or arrangements for safe harbor protection.

g. Coordination and Management of Care

Summary of OIG Proposed Rule: We proposed to define ''coordination and management of care,'' the first of the four value-based purposes, as the deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population. In defining this term, we sought to distinguish between referral arrangements, which would not be protected, and legitimate care coordination arrangements, which naturally involve referrals across provider settings but also include beneficial activities beyond the mere referral of a patient or ordering of an item or service. We expressed particular concern about distinguishing between coordinating and managing patient care transitions for the purpose of improving the quality of patient care or appropriately reducing costs, on one hand, and churning patients through care settings to capitalize on a reimbursement scheme or otherwise generate revenue. We proposed in preamble that we would not consider the provision of billing or administrative services to be the coordination and management of patient care.

Summary of Final Rule: We are finalizing, with modifications, the definition of ''care coordination and management.'' First, we have revised the definition to clarify that the deliberate organization of patient care activities and sharing of information must occur between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients. Second, in response to comments, we have revised the description of the required goals to state that the parties' efforts (*i.e.,* the deliberate organization of patient care activities and sharing of information) must be designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population. These two changes clarify the regulatory language with respect to the parties that engage in the care coordination and management to include the VBE itself, which can be party to a value-based arrangement, and make clear that efforts to improve efficiency can be part of coordination and management of care. Third, also in response to comments, we have revised the definition to clarify that the term does not require achievement of the stated goals, but rather that the efforts must be designed to achieve such goals.

Comment: Commenters on this topic varied in their responses to our proposed definition of ''coordinating and managing care.'' While we received some comments expressing support, others asserted that the definition was superfluous. A commenter highlighted that existing CMS programs already rely on similar terminology and encouraged OIG to align its definition.

Response: For the reasons stated in the OIG Proposed Rule, we are finalizing a definition of ''coordination and management of care.'' Among other things, this definition helps ensure that protected arrangements serve patients and the goals of coordinated care. Further, given the importance of this value-based purpose in the safe harbors, the definition provides a standard against which safe harbor compliance can be measured. This is intended to help providers seeking to comply with the safe harbors. As noted in the OIG Proposed Rule, we considered other agency definitions in crafting ours.[27]

Although other laws and regulations, including the physician self-referral law and associated regulations, may utilize the same or similar terminology, the definition and interpretations we are adopting in this rule would not affect CMS's (or any other governmental agency's) interpretation or ability to interpret such term.

Comment: At least two commenters opposed our proposed definition because they believe it would require

[27] 84 FR 55707 (Oct. 17, 2019). For example, the Agency for Healthcare Research and Quality explains that ''[c]are coordination is identified by the Institute of Medicine as a key strategy that has the potential to improve the effectiveness, safety, and efficiency of the American health care system. Well-designed, targeted care coordination that is delivered to the right people can improve outcomes for everyone: patients, providers, and payers.'' *https://www.ahrq.gov/ncepcr/care/coordination.html.*

constant achievement. As an alternative, these commenters proposed revising the definition of ''coordination and management of care'' from the deliberate organization of patient care activities and sharing of information in order to improve health outcomes, to the deliberate organization of patient care activities and sharing of information in an attempt to improve health outcomes.

Response: We thank commenters for highlighting this issue. It was not our intent for the definition of ''coordination and management of care'' to require constant achievement of improved health outcomes. To address the issue raised by the commenters and reduce the potential for confusion, we have revised the definition to clarify that the organization of patient care activities and the sharing of information must be *designed to* achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population. Actual achievement of safer, more effective, or more efficient care that improves health outcomes is not required. However, the parties must ensure that their efforts (*i.e.,* deliberate organization of patient care activities and sharing of information) are designed to achieve these goals.

Comment: Several commenters questioned whether: (i) Patient monitoring, patient diagnostic activities, patient treatment, and communication related to such patient activities; or (ii) predictive analytics, would constitute the coordination and management of care.

Response: Depending on the facts and circumstances, each of the actions listed above could qualify as the coordination and management of care. We intend for the coordination and management of care to require beneficial activities beyond the mere referral of a patient or ordering of an item or service. Coordination and management of care requires some additional, deliberate effort and sharing of information, across two or more parties, that is designed to augment care delivery to achieve safer, more effective, or more efficient care to improve health outcomes.[28] For example, the ordering of a diagnostic test, such as an imaging study, by a provider and the sharing of the test results back to the ordering provider would not, without additional beneficial activities, constitute the coordination and management of care under the finalized definition. If, however, the ordering of the imaging study and the sharing of results was part of a more deliberate, organized effort between or among the parties to achieve safer and more effective care and improve health outcomes, such as by implementing protocols to reduce the number of redundant tests or ensuring that test results are readily shared with and available to the patient and all members of the patient's caregiver team and used to inform care decisions, then the arrangement may constitute coordination and management of care. We also emphasize that the definition requires not only the deliberate organization of patient care activities, but also the sharing of information between (or among) the parties who are coordinating and managing care. This information sharing must be part of a design to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.

Our final rule endeavors to encompass a wide range of beneficial care coordination activities, with limitations. As described in the OIG Proposed Rule, coordination might occur between hospitals and post-acute care providers, specialists and primary care providers, or hospitals and physician practices and patients. It could involve using care managers, providing care or medication management, creating a patient-centered medical home, helping with effective transitions of care, sharing and using health data to improve outcomes, or sharing accountability for the care of a patient across the continuum of care. These arrangements often naturally involve referrals across provider settings but include beneficial activities beyond the mere referral of a patient or ordering of an item or service. We see a clear distinction between coordinating and managing patient care transitions for the purpose of improving the quality of care or improving efficiencies, which would fit in the definition, and churning patients through care settings to capitalize on a reimbursement scheme or otherwise generate revenue, which would not fit in the definition. The OIG Proposed Rule cites a relevant example of cycling patients through skilled nursing facilities (SNFs) to maximize revenue as the kind of arrangement we do not intend to fit in the definition or receive protection under any safe harbor.

Comment: In response to OIG's solicitation of comments on the intersection of coordination and management of care and cybersecurity, a commenter stated that cybersecurity items or services should meet the definition of ''coordination and management of care.'' According to the commenter, cybersecurity items or services may be needed to share information between or among VBE participants, and the commenter expressed concern that parties would overlook opportunities to work with small practices that cannot afford proper cybersecurity tools.

Response: We appreciate the commenters' input; however, we respectfully disagree with their recommendation. As a general matter, the use or sharing of cybersecurity items and services alone would not meet the definition of ''coordination and management of care.'' Having reviewed the comments and upon further consideration of the issue, we view the use or sharing of such items and services to be focused on ensuring the security of patient care items and related information exchange, rather than the deliberate organization of patient care activities and sharing of information, as required by the definition of ''coordination and management of care.'' That being said, an arrangement involving the exchange of health information technology that incorporates cybersecurity items and services could meet the definition of ''coordination and management of care.'' For example, where a VBE participant provides data analytics software to another VBE participant to facilitate the VBE participants' coordination and management of care, security features to control access to data included within that software would not preclude the data analytics software from meeting the definition of ''coordination and management of care.'' However, we note that meeting the definition of ''coordination and management of care'' does not, de facto, afford safe harbor protection; for safe harbor protection, the remuneration exchanged must squarely satisfy all safe harbor conditions.

The use or sharing of cybersecurity items and services alone may meet other value-based purposes, and such remuneration may be eligible for protection under the substantial downside financial risk safe harbor (paragraph 1001.952(ff)) or full financial risk safe harbor (paragraph 1001.952(gg)). The cybersecurity technology and related services safe

[28] *See, e.g.,* NEJM Catalyst, *What is Care Coordination?* (Jan. 1, 2018), *https://catalyst.nejm,org/what-is-care-coordination/* (providing examples and noting that ''[c]are coordination synchronizes the delivery of a patient's health care from multiple providers and specialists. The goals of coordinated care are to improve health outcomes by ensuring that care from disparate providers is not delivered in silos, and to help reduce health care costs by eliminating redundant tests and procedures.'').

harbor, paragraph 1001.952(jj), also is available to protect the exchange of cybersecurity items and services, provided all safe harbor requirements are met.

Comment: In lieu of making the coordination and management of patient care a requirement specific to the value-based safe harbors and arrangements for patient engagement and support safe harbor, a commenter requested that OIG revise the definition of ''value-based purpose'' to reflect that one of the value-based purposes must be the coordination and management of patient care.

Response: We appreciate the commenter's input; however, we decline to adopt the commenter's suggestion for two reasons. First, the current structure facilitates alignment between OIG's and CMS's value-based terminology to ease burden on providers and others working to comply with both sets of rules. In addition, as finalized, the substantial downside financial risk and full financial risk safe harbors already provide parties with additional flexibility to identify value-based purposes other than the coordination and management of care, in defined circumstances.

Comment: A commenter requested clarification as to the types of activities that constitute the provision of billing or administrative services. This commenter asserted certain administrative services, such as the more effective management of patient records, could improve the coordination and management of patient care and should be not be excluded from the definition of ''value-based purpose.''

Response: Administrative services, depending on the facts and circumstances, may meet the definition of ''coordination and management of care.'' We are clarifying our statement in the OIG Proposed Rule that we would not consider the provision of billing or administrative services to be the management of patient care [29] to make clear that we view any billing or financial management services arrangement that is characterized as facilitating the coordination and management of patient care to be outside the scope of this definition for purposes of this rule. By financial management services, we mean services such as bookkeeping operations, contract management, revenue cycle management, or other similar activities. These activities might complement the organization of patient care activities, but they are not the type of care coordination activities contemplated in our proposed rule or covered by the final definition.

We also are mindful that, in certain situations, the remuneration exchanged by the parties might incidentally assist the recipient with performing certain of these administrative functions. However, we believe that any benefit that the remuneration has on the administrative activities of the recipient should be incidental, at most. This approach helps ensure that value-based arrangements eligible for safe harbor protection focus on the delivery of care to patients. Arrangements that focus on billing and financial management services arrangements may be structured to fit in another safe harbor, such as the safe harbor for personal services and management contracts, which includes protections such as a fair market value requirement. The value-based safe harbors are not intended to protect billing and financial management services arrangements, even those that might help support care coordination and management, that are not fair market value under the guise of a value-based arrangement.

We address this issue through a new provision in the care coordination arrangements safe harbor at paragraph 1001.952(ee)(1)(iii)(A), which provides that the remuneration exchanged pursuant to a value-based arrangement may not be exchanged or used more than incidentally by the recipient for the recipient's billing or financial management services. We are not adopting parallel provisions in the substantial downside financial risk or full financial risk safe harbors because there are circumstances in which billing and financial management services could be included in the remuneration that is protected by those safe harbors. For this same reason, we are not incorporating this limitation into the definition of coordination and management of care, which applies across all of the value-based safe harbors.

Comment: A commenter suggested that we revise this term to require the ''coordination *or* management of care'' instead of the ''coordination and management of care.''

Response: We appreciate the commenter's input; however, we are not adopting the commenter's suggestion. The coordination and management of care reflects an integrated set of activities for patients, as set out in the definition we are finalizing in this rule. We are concerned that management activities, standing alone, would not be appropriately patient-focused to achieve the intent of the value-based safe harbors.

Comment: A commenter appeared to request that OIG revise its definition of ''coordination and management of care'' to provide that the deliberate organization of patient care activities and sharing of information may be between VBE participants and patients' family members or caregivers, in addition to those activities being conducted between VBE participants and patients.

Response: We would consider the deliberate organization of patient care activities and sharing of information between VBE participants and patients' family members or others acting on the patients' behalf to meet the definition of ''coordination and management of care.'' This may include, for example, intervening caregivers, and family members, such as for patients who are children. We note that an arrangement that is solely between a VBE participant and a patient might constitute the coordination and management of care, but it would not fit in the value-based safe harbors because those safe harbors do not protect the exchange of remuneration with patients. Other safe harbors may protect the exchange of remuneration with patients, including the patient engagement and support safe harbor at paragraph 1001.952(hh). Arrangements between VBEs and one or more of their VBE participants or between or among VBE participants that engage patients in efforts to coordinate and manage care could qualify under the value-based safe harbors with respect to remuneration flowing between a VBE and VBE participant or between VBE participants if all safe harbor conditions are met. For purposes of the care coordination arrangements safe harbor, parties exchanging remuneration pursuant to the value-based arrangement would need to be part of the coordination and management of care of the target patient population in some fashion, although levels of involvement in care coordination may differ among VBE participants, depending on the scope and nature of the arrangement.

3. Care Coordination Arrangements To Improve Quality, Health Outcomes, and Efficiency Safe Harbor (42 CFR 1001.952(ee))

a. General Comments

Summary of OIG Proposed Rule: We proposed a new safe harbor at proposed paragraph 1001.952(ee) to protect in-kind remuneration exchanged between qualifying VBE participants with value-based arrangements that squarely satisfy all of the proposed safe harbor's requirements. We developed this safe

[29] 84 FR 55707 (Oct. 17, 2019).

harbor to facilitate value-based care and improved care coordination for patients by providers and others that may be assuming no or less than substantial downside financial risk.

Proposed conditions included commercial reasonableness (proposed paragraph 1001.952(ee)(2)), written documentation (proposed paragraph 1001.952(ee)(3)), record retention (proposed paragraph 1001.952(ee)(11)), and establishment and monitoring of outcomes measures (proposed paragraph 1001.952(ee)(1)). We proposed that protected remuneration would be used primarily to engage in value-based activities that are directly connected to the coordination and management of patient care for the target patient population (proposed paragraph 1001.952(ee)(4)(ii)). We further proposed that arrangements could not induce VBE participants to furnish medically unnecessary care or reduce or limit medically necessary care (proposed paragraph 1001.952(ee)(4)(iii)); could not be funded by outside sources (proposed paragraph 1001.952(ee)(4)(iv)); could not limit medical decision-making or patient freedom of choice (proposed paragraphs 1001.952(ee)(7)(ii)–(iii)); could not take into account the volume or value of business outside the value-based arrangement (proposed paragraph 1001.952(ee)(5)); and could not include marketing of items or services to patients or patient recruitment activities (proposed paragraph 1001.952(ee)(7)(iv)). We proposed a requirement that the recipient of the remuneration would pay at least 15 percent of the offeror's cost of the remuneration (proposed paragraph 1001.952(ee)(6)). We also proposed a requirement that arrangements be terminated within 60 days if the VBE's accountable body or person determined that the arrangements were unlikely to further coordination and management of care, were not achieving the value-based purpose or were resulted in material deficiencies in quality of care (proposed paragraph 1001.952(ee)(9)). In addition, we proposed that an exchange of remuneration would not be protected under the care coordination arrangements safe harbor if the offeror knows or should know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose (proposed paragraph 1001.952(ee)(10)). These conditions were proposed to minimize risks of traditional fee-for-service fraud and abuse and pay-for-referral schemes, particularly in arrangements where the parties are not assuming downside risk.

Summary of Final Rule: We are finalizing, with modifications, this safe harbor. The safe harbor continues to protect in-kind remuneration exchanged between a VBE and VBE participant or between VBE participants pursuant to a value-based arrangement that squarely satisfies all of the proposed safe harbor's requirements. We have modified and clarified many of the safe harbor requirements in response to public comments, as described below. The safe harbor includes conditions related to commercial reasonableness, outcomes measures, written documentation, record retention, monitoring, termination, marketing and patient recruitment, and diversion and reselling of remuneration. The safe harbor requires that protected remuneration be used predominately to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. Protected arrangements cannot induce VBE participants to furnish medically unnecessary care or reduce or limit medically necessary care; cannot limit medical decision-making or patient freedom of choice; and cannot take into account the volume or value of business outside the value-based arrangement. Under the final rule, all recipients must pay 15 percent of the offeror's cost or 15 percent of the fair market value of the remuneration. We are not finalizing the proposed condition related to outside funding of the remuneration.

As detailed in section III.B.2.e and III.B.2.g of this preamble relating to the VBE participant definition, we are carving out patients and certain entities from the safe harbor; those entities are listed at paragraph 1001.952(ee)(13). We are finalizing a limited pathway for safe harbor protection in the care coordination arrangements safe harbor for manufacturers of devices and medical supplies and DMEPOS companies participating in digital health technology arrangements at paragraph 1001.952(ee)(13). As discussed in section III.B.2.e.vi of this preamble, we are finalizing a condition in the care coordination arrangements safe harbor that restricts those entities from conditioning the exchange of remuneration on any recipient's exclusive use, or minimum purchase, of any item or service manufactured, distributed, or sold by those entities.

This safe harbor protects in-kind remuneration only. Some monetary compensation associated with care coordination or value-based activities may be protected under other safe harbors, such as the other value-based safe harbors or the safe harbor for personal services and management contracts and outcomes-based payments at paragraph 1001.952(d).

Comment: Many commenters expressed support for the care coordination arrangements safe harbor and the existence of a value-based safe harbor that did not mandate the assumption of downside financial risk. These commenters stated the safe harbor would facilitate innovative arrangements to improve care coordination and facilitate community partnerships. Other commenters, while generally supportive of the safe harbor, asserted that it included too many burdensome, complex, and subjective conditions; these commenters urged OIG to reduce the number of requirements in the safe harbor. Conversely, some commenters opposed the safe harbor, with their concerns largely falling into two categories: (i) The potential for fraud and abuse because the safe harbor does not require the parties to assume downside risk or that there are not strong enough program integrity guardrails; and (ii) negative effects on competition, *i.e.,* unduly benefiting larger providers.

Response: We thank commenters for their feedback. The safe harbor is intended to protect arrangements by parties who are transitioning to higher levels of risk or who are engaging in care coordination that improves quality and efficiency, without assuming risk. We agree with commenters that there could be increased risk of fraudulent or abusive behavior (*e.g.,* overutilization) where providers who order items or services are not at substantial downside financial risk. We structured the care coordination arrangements safe harbor to reflect and mitigate that increased risk. The safe harbor includes requirements tailored to ensure that arrangements protected by the safe harbor—which could apply to remuneration exchanged between parties who refer Federal health care program business to each other and where both parties are paid by Federal health care programs on a fee-for-service basis—do not result in the traditional FFS fraud and abuse risks. As described in the OIG Proposed Rule, traditional FFS fraud and abuse risks include inappropriately increased costs to the Federal health care programs or patients, corruption of practitioners' medical judgment, overutilization, inappropriate patient steering, unfair competition, or poor-quality care.[30]

We aimed to finalize a safe harbor that is not administratively burdensome, overly complex, or subjective, but we

[30] 84 FR 55696 (Oct. 17, 2019).

acknowledge that parties must satisfy a number of criteria to receive safe harbor protection and that some parties may find the safe harbor administratively burdensome, overly complex, and subjective with respect to their particular arrangements. However, we believe that these conditions, taken together, ensure the safe harbor protects legitimate value-based arrangements, fosters improved care coordination, allows for innovation, adequately addresses the traditional FFS risks described above, and limits potentially problematic referral schemes. We acknowledge that larger entities may be better positioned to afford some types of investments required by value-based activities, but we have intentionally crafted this safe harbor for a wide range of care coordination arrangements, including arrangements between small entities, providers serving rural and underserved communities, or both, that might not require substantial investment. As we describe elsewhere, many of the conditions are flexible (*i.e.,* not one-size-fits-all) and can be satisfied in ways that take into account the size of, and resources available to, VBE participants.

Comment: A commenter proposed that, in lieu of the care coordination arrangements safe harbor, OIG enumerate acceptable value-based arrangements that are of minimal monetary value to the referral source.

Response: We did not propose to adopt a list of acceptable value-based arrangements of minimal monetary value in lieu of the care coordination arrangements safe harbor, and we are not adopting any such list as part of this final rule.

Comment: A primary care provider requested that we address whether or not it would be permissible to waive cost-sharing amounts for select services under the care coordination arrangements safe harbor.

Response: As a threshold matter, whether cost-sharing is owed for a particular service covered by Medicare or Medicaid is programmatic policy under the auspices of CMS and state Medicaid programs. If cost-sharing is owed by the beneficiary under the applicable programmatic rules and a provider or supplier waives any such obligations, then a question arises about whether any benefit stemming from the waiver of the beneficiary's cost-sharing obligations implicates the Federal anti-kickback statute or the Beneficiary Inducements CMP.

Cost-sharing waivers furnished to patients would not qualify for protection under the care coordination arrangements safe harbor. First, cost-sharing waivers are not in-kind remuneration, and the care coordination arrangements safe harbor is limited to exchanges of in-kind remuneration. Second, as explained further in section III.2.e.i of this preamble, the context and framework of the value-based provisions in the OIG Proposed Rule made clear that we did not intend patients to be VBE participants who could engage in value-based arrangements under the value-based safe harbors. We are finalizing, as proposed, that the care coordination arrangements safe harbor is available to protect only the exchange of in-kind remuneration between parties to a value-based arrangement, not remuneration exchanged with patients. In response to comments and for clarity, we have: (i) Revised the definition of ''VBE participant'' to expressly exclude patients; and (ii) revised the introductory language of the paragraph to expressly limit protection to exchanges of remuneration between a VBE and VBE participant or between VBE participants.

In some cases, other existing protections may be available for some cost-sharing waivers, including cost-sharing waivers by certain entities that are not offered as part of any advertisement or solicitation; are not routine; and are made following an individual determination of financial need.[31]

Comment: A hospital association requested that the care coordination arrangements safe harbor include a 12-month preparation period that would be analogous to the ''phase-in'' periods in the substantial downside financial risk and full financial risk safe harbors. Similarly, at least two commenters requested that OIG protect initial investments in value-based arrangements or activities by parties exploring the creation of a VBE, with a commenter requesting that OIG protect such remuneration prior to any terms being set forth in a written agreement.

Response: We are not adopting the suggestion for a preparation or ''phase-in'' period for the care coordination arrangements safe harbor. There may be practical or operational reasons for parties to engage in financial arrangements or make ''phase-in'' investments as they explore creating a VBE or before committing to a particular value-based arrangement with partners. On balance, however, these considerations do not outweigh the heightened risk of fraud or abuse during a ''phase-in'' period in advance of the commencement of a value-based arrangement, particularly in situations where parties have not yet created a VBE with its attendant accountability and transparency protections. Moreover, it is OIG's belief that the need for a ''phase-in'' period is lower in the context of this safe harbor compared to the risk-based safe harbors because this safe harbor is limited to in-kind remuneration and does not require the assumption of risk. We allow for a preparation or ''phase-in'' period in the two risk-based safe harbors because we recognize that parties to a value-based arrangement may need to exchange remuneration during a period of time before the VBE formally takes on downside financial risk in order to prepare the VBE and the VBE participants for that assumption of risk. The same context does not exist for the care coordination arrangements safe harbor because it does not require the assumption of risk. We note, however, that parties may be able to structure some preparatory arrangements to fit in this safe harbor, provided that a proper VBE and value-based arrangement have been established and all other safe harbor requirements are met, including the requirement that any exchange of remuneration be used predominantly to engage in value-based activities. Parties may also look to other potentially available safe harbors for preparatory arrangements.

Comment: Multiple commenters requested clarification on, and examples regarding, the types of entities and activities that could qualify for protection under the care coordination arrangements safe harbor. For example, a commenter requested that OIG expressly protect income guarantees for physicians transitioning from traditional compensation schemes to value-based models.

Response: With respect to the question regarding income guarantees, income guarantees are not in-kind remuneration and would therefore not qualify for protection under the care coordination arrangements safe harbor. While neither exhaustive nor sufficiently detailed to allow for a comprehensive analysis of the arrangement under the Federal anti-kickback statute and the care coordination arrangements safe harbor, we provide the following high-level examples to illustrate arrangements that could be structured to satisfy the conditions of the care coordination arrangements safe harbor.

First, to coordinate care and better manage the care of their shared patients,

[31] *See, e.g.,* 42 U.S.C. 1320a–7b(b)(3)(D), (G); 42 CFR 1001.952(k); OIG, Special Fraud Alert: Routine Wavier of Copayments or Deductible Under Medicare Part B, 59 FR 65372, 65377 (Dec. 19, 1994), *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.*

a specialty physician practice may wish to provide data analytics items (*e.g.,* software designed to present certain data) and services (*e.g.,* conducting data analysis) to the primary care physician practice with which it works closely and from which it receives referrals for consultations and federally reimbursable items and services. The data analytics items and services could, for example, identify practice patterns that deviate from evidence-based protocols or confirm whether followup care recommended by the specialty physician practice is being sought by patients or furnished by the primary care physician group. This provision of data analytics items and services could be structured to satisfy the care coordination arrangements safe harbor.

Second, hospitals and physicians could work together in new ways to coordinate and manage care for patients being discharged from the hospital. The hospital might provide a physician group with care managers (who identify the physician group's high-risk patients and help manage patients' care transitions, medications, and home-based care) to ensure patients receive appropriate followup care post-discharge; data analytics systems to help the group's physicians ensure that their patients are achieving better health outcomes; and remote monitoring technology to alert the group's physicians when a patient needs a health care intervention to prevent unnecessary emergency room visits and readmissions.

Third, a medical technology company could partner with physician practices, to better coordinate and manage care for patients discharged from a hospital with digitally-equipped devices that collect and transmit data to the physicians to help monitor the patients' recovery and flag the need to intervene in real time (*e.g.,* a device that monitors range of motion that could inform what an appropriate physical therapy intervention may be). The technology company could provide the physician group with necessary digital health technology that improves the physician group's ability to observe recovery and intervene, as necessary.

We remind parties seeking to structure an arrangement to satisfy the care coordination arrangements safe harbor that compliance with the safe harbor requires a fact-specific assessment. In addition, we remind stakeholders that the advisory opinion process remains available for parties seeking to determine whether a particular arrangement satisfies the care coordination arrangements safe harbor or for parties that would like to request prospective protection for an arrangement that does not squarely satisfy the terms of the safe harbor.

Comment: A commenter appeared to believe that the statement in the OIG Proposed Rule that ''each offer of remuneration must be analyzed separately for compliance with the safe harbor'' [32] requires each value-based arrangement to be reviewed by the Department, with the potential for the Department to deny safe harbor protection for any proposal.

Response: If there are multiple streams of remuneration flowing under a single value-based arrangement, the parties would need to evaluate each such stream separately to assess compliance with the safe harbor (or, as appropriate, other available safe harbors). In the context of an enforcement action, the government would likewise analyze each such stream separately, and consider the totality of the arrangement, to assess potential liability under the Federal anti-kickback statute. The care coordination arrangements safe harbor does not require, nor do any of our other value-based safe harbors require, the submission of the value-based arrangement to the Department for review.

Comment: Many commenters urged OIG to align the care coordination arrangements safe harbor with CMS's value-based exception to the physician self-referral law, with some asserting that the different requirements in each would increase regulatory complexity and pose a barrier to the advancement of value-based care. To facilitate alignment, commenters suggested that OIG permit monetary remuneration, remove any contribution requirement, or adopt CMS's definition of ''commercial reasonableness.'' A commenter appeared to request that OIG and CMS both include a provision requiring a signed agreement.

Response: We aligned our safe harbors with the exceptions being adopted by CMS as part of the Regulatory Sprint wherever possible. For the reasons discussed in greater detail in section III.A.1, complete alignment is not appropriate, including with respect to most of the provisions of the care coordination arrangements safe harbor referenced by commenters. In particular, the contribution and exclusion of monetary remuneration serve to reduce risk of intentional kickback schemes for reasons explained more fully in the preamble discussions of each requirement, sections III.B.3.g (contribution requirement) and III.B.3.e.i (in-kind remuneration). Specific to the recommended expansion of the safe harbor to protect monetary remuneration, we continue to believe that providing safe harbor protection for monetary remuneration presents heightened fraud and abuse risks that outweigh the potential benefits to Federal health care programs and patients. This is particularly true where remuneration is exchanged between parties that are not required to assume substantial financial risk, and the protected remuneration is not required to be fair market value and may take into account the volume or value of referrals for the target patient population. Consistent with this concern, the new safe harbor for outcomes-based payments at paragraph 1001.952(d)(2), which is available for monetary remuneration, includes a fair market value requirement and a limitation on directly taking into account the volume or value of referrals. With respect to the commenter's request that OIG and CMS align their respective signed writing requirements, we are finalizing a requirement that the terms of the value-based arrangement must be set forth in writing and signed by the parties, and we make clear that the writing requirement can be satisfied by a collection of documents, which aligns with the writing requirement in CMS's value-based exception.

b. Outcome Measures

Summary of OIG Proposed Rule: We proposed to provide flexibility in selecting outcome measures given the range of arrangements that may be covered by the proposed safe harbor. We proposed in proposed paragraph 1001.952(ee)(1) to require parties to establish one or more specific evidence-based, valid outcome measures to serve as benchmarks for assessing the recipient's performance under the value-based arrangement and advancement toward achieving the coordination and management of care for the target population. The measures would not include patient satisfaction or convenience measures. We expressed our view that outcome measures should reflect more than maintenance of the status quo and considered requiring that outcomes measures drive meaningful improvements in quality, health outcomes, or efficiencies, whether by driving improvements that are measurable or that are more than nominal in nature. We indicated that we were considering for the final rule and solicited comment on whether we should require rebasing of the outcome

[32] 84 FR 55708 (Oct. 17, 2019).

measure (*e.g.,* resetting the benchmark).[33]

Summary of Final Rule: We are finalizing, with modifications, the outcome measures requirement at paragraph 1001.952(ee)(4). The modifications are based on public comments. The final rule requires that the parties to a value-based arrangement establish one or more legitimate outcome or process measures that the parties reasonably anticipate will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health science support. The measure(s) must: (i) Include one or more benchmarks related to improving, or maintaining improvement, in the coordination and management of care for the target patient population; (ii) relate to the remuneration exchanged under the value-based arrangement; and (iii) not be based solely on patient satisfaction or patient convenience. The outcome or process measure and its benchmark must be monitored, periodically assessed, and prospectively revised, as necessary, so that working towards the measure continues to advance the coordination and management of care of the target patient population.

Comment: Commenters generally supported the outcome measures requirement, as proposed. However, some commenters opposed requiring the parties to establish outcome measures against which a party would be measured under a value-based arrangement. For example, the commenters asserted that requiring the establishment of outcome measures would be administratively burdensome, would be confusing, and would not reflect the lack of valid outcome measures for many specialty practices. Some commenters asked OIG for an exception to the requirement for small and rural-based VBE participants and Indian health care providers. A commenter representing Indian health care providers requested that they be carved out from the outcome measures requirement because of a concern that the outcome measures would not be aligned with already reported Tribal outcome measures and would become an unnecessary administrative burden on understaffed Indian health care providers. Other commenters suggested that OIG should not finalize the outcome measures requirement because the writing requirement in the care coordination arrangements safe harbor is sufficient to protect against fraud and abuse.

[33] 84 FR 55708 (Oct. 17, 2020).

Response: As noted in the OIG Proposed Rule, inclusion of a meaningful outcome measure in a protected value-based arrangement will help ensure that the arrangement is designed to advance care coordination and serves the needs of the target patient population. As explained below, we have revised the requirement in the final rule to increase flexibility, broaden options for meeting the requirement, and reduce administrative burden, including on rural and small providers and on Indian health care providers. Our revised approach also addresses the comment regarding lack of standards for specialty practices because we are not requiring use of industry standard measures. Specialty practices may create measures using a range of data, information, and sources, including internally generated data and information, provided that, among other requirements, the measures are based on clinical evidence, credible medical support, or credible health science support, include an appropriate benchmark, and relate to the remuneration being provided under the arrangement. This last requirement helps ensure, as we explained in the OIG Proposed Rule, that the measure bears a close nexus to the value-based activities in the value-based arrangement and the needs of the target patient population.

We are not aware of any impediment to Indian health care providers using existing outcomes measures that they are already required to report; nothing in the safe harbor requires development of new measures if existing measures meet the final rule requirements.

We do not agree that a writing requirement is a sufficient safeguard against fraud or abuse based on our enforcement experience. While documentation is important for transparency and compliance verification, it does not prevent fraud or abuse or ensure that arrangements are carried out in accordance with their terms or serve their intended purposes.

Comment: Commenters varied in their responses to the terminology we proposed in the outcome measures requirement (''specific evidenced-based, valid outcome measures''). For example, commenters asked OIG to define ''outcome measure'' and ''evidence-based.'' A commenter supported the concept of ''evidence-based'' outcome measures, stating that OIG's proposal would provide needed flexibility to allow both clinical and non-clinical outcome measures and to allow participants to select up-to-date outcome measures, such as measures related to social determinants of health. Other commenters pointed out the significant time and resources needed, particularly for smaller VBEs and VBE participants, to undertake studies or gather and document evidence for novel interventions and to develop, implement, and monitor evidence-based measures. Some commenters explained that using ''evidence-based'' as the standard would chill innovation by precluding innovative models for which evidence does not already exist or value-based arrangements that are currently pilots or demonstrations intended to develop evidence. A commenter expressed concern that conditioning safe harbor protection on ''valid'' outcome measures was too subjective and recommended the outcome measures be ''clinically meaningful,'' which could be based on measurable data or real-world evidence.

Response: We have reconsidered our use of the term ''evidence-based'' in this rule. Our use of the term may have indicated a level of scientific rigor and resource investment beyond what we intended for purposes of this safe harbor, which is intended to be available for experienced and new entrants into value-based care, including those not yet ready to assume financial risk, and to promote innovation in care delivery. We intended to include a standard that captured clinical and non-clinical measures (including measures related to quality of care, process improvements, efficiency in care delivery, and social determinants of health), while also allowing for innovation. We did not intend to require that protected arrangements be grounded in experimental research, randomized clinical trials, best available evidence, or other similar characteristics often associated with the term ''evidence-based'' in common definitions. We did not intend to be overly restrictive or to require strict scientific evidence of the utility of an outcome measure. Having considered the comments, common definitions, and input from Department experts, we are persuaded that the term ''evidence-based'' was overly restrictive and not the best term to describe the outcome measures we envisioned for purposes of this rule.

We have likewise reconsidered our use of the terms ''valid'' and ''specific'' in the OIG Proposed Rule. These terms dovetailed with our use of ''evidence-based'' and were intended to convey that the selected outcome measures needed to be grounded in legitimate, verifiable data, or other information. That is, we intended that selected measures be legitimate and not sham measures used to justify an illegitimate

exchange of remuneration. Our intent is that selected measures be credible and appropriate for the care coordination and management purpose of the arrangement. Upon further consideration, the term ''legitimate''—and its common sense meaning—better effectuates our intent, and we use that term in the final rule.

Accordingly, in this final rule, we are revising the requirement that parties establish one or more specific evidence-based, valid outcome measures. Under the final rule, the parties to a value-based arrangement must establish one or more legitimate outcome or process measures that the parties reasonably anticipate will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health science support. The terms ''clinical evidence or credible medical or health science support,'' better reflect our intent to have a reasonable, flexible standard applicable to a wide range of arrangements and to allow selection of measures based on scientific, clinical, medical, social science, or industry quality standards, or other legitimate, verifiable data or information, whether internal to the VBE or externally generated. By use of the term ''health science'' we intend to include public health, health informatics, research and development, and sciences that look at the treatment and prevention of diseases. Unlike the new protection provided within the personal services and management contracts safe harbor for outcomes-based payments, in this safe harbor parties may rely on credible health science as well as credible medical support, reflecting that this safe harbor covers a wider variety of care coordination arrangements (including remuneration in the form of health technology) and protects only in-kind remuneration, rather than monetary payments, presenting relatively lower overall risk.

The revised requirement continues to encompass both clinical and non-clinical measures, and internal or externally generated measures, and will allow participants to select up-to-date outcome or process measures over time. Under the final rule, parties will be required to document the measures they select and the clinical evidence, credible medical support, or credible health science support upon which they relied in making the selection by providing a description of the measures in a signed writing.

Comment: Some commenters requested clarification from OIG regarding how parties should select outcome measures, and others asked for additional flexibility in the selection of outcome measures. For example, parties asked OIG to permit both internally developed measures, *i.e.,* measures that do not require validation in a medical journal or by another third-party source, and process-based measures, such as providing or not providing a specific treatment to improve patient outcomes or safety. A commenter asserted that outcome measures should be anticipated to advance the coordination *or* management of care of the target patient population rather than the coordination *and* management of care of individual patients. Another commenter opposed the requirement for outcome measures to advance the coordination and management of care altogether, stating that care coordination is process-based, not outcomes-based.

Other commenters expressed concern that too much flexibility for parties to select outcome measures could lead parties to use subjective measures that do not improve patient outcomes or are otherwise abusive. A commenter suggested OIG require that: (i) Value-based arrangements advance the coordination and management of care for the target patient population; and (ii) in any dispute concerning the applicability of this safe harbor, the VBE will bear the burden of proving, based upon objective evidence, that the value-based arrangement advanced the coordination and management of care of the target patient population. Some commenters asked OIG to include an express requirement in the final rule that outcome measures be designed to drive meaningful improvements in quality, health outcomes, or efficiencies in care delivery. Others supported a requirement for parties to establish more than one outcome measure or only measures reflecting the outcomes most important to patients.

A commenter recommended that parties be able to assess performance toward achieving outcome measures with respect to the entire patient population of an integrated delivery system instead of a subset of that population. A commenter asked OIG to address issues regarding individual physician participant measurement compared to group measurement. The commenter expressed concern that individual physicians may not have sufficient influence on the development of outcome measures for their target patient population and that physician-level measures can be challenging to develop (including because of small sample size and appropriate accountability of individual physicians).

Response: We are modifying the requirement to clarify that parties must select one or more legitimate outcome or process measures based on clinical evidence, credible medical support, or credible health science support. Parties must reasonably anticipate that the measures they select will advance the coordination and management of the care of the target patient population, which is the focus of this safe harbor. The revised measure selection standard offers greater flexibility and opportunities for innovation over time. The final rule permits clinical and non-clinical measures, internally or externally developed.

Under the final rule, the outcome or process measures do not need to be independently validated by a medical or other journal or another third-party source. They can be process-based, such as, for example, a measurement of the number of patients with diabetes that had their blood pressure tested, and we are modifying the regulatory text to clarify this. Unlike the new protection under the personal services and management contracts safe harbor for outcomes-based payments, which requires parties to achieve an outcome measure to receive payment (the outcome measure may have a process component), the care coordination arrangements safe harbor measure requirement offers greater flexibility. It is broader in recognition that the safe harbor: (i) Protects only in-kind remuneration, such as health technology, for which process measures may be the most legitimate and useful type of measure; and (ii) is available to VBE participants that are not taking on risk for achieving outcomes.

In response to the assertion that outcome measures should be anticipated to advance the coordination *or* management of care of the target patient population rather than the coordination *and* management of care, we addressed, and rejected, a similar suggestion in section III.2.B.g regarding changing ''and'' to ''or'' in the definition of coordination and management of care. Because the condition requiring parties to establish outcome measures incorporates the definition of ''coordination and management of care'', it is appropriate to use that defined term, which, for the reasons offered above, includes an ''and'' rather than an ''or.''

Where available, use of measures validated by a credible third party would be a prudent practice, but this is not required. We confirm that parties can select a measure applicable to the entire target patient population or select a different outcome or process measures for different segments of the target patient population (*e.g.,* the measure for

organ transplant patients within a target patient population may differ from the appropriate measure for a non-transplant patient). In such circumstances, the parties must (among other criteria) reasonably anticipate that all such measures collectively will advance the coordination and management of care for the entire target patient population. With respect to selecting the target patient population, we refer readers to that section of this preamble, section III.B.2.c.

We are further modifying our proposed rule to respond to the comments and our own concerns regarding parties selecting measures in a way that does not improve patient care or that could be abusive. In the OIG Proposed Rule, we considered requiring that outcome measures drive meaningful improvements in quality, health outcomes, or efficiencies, whether by driving improvements that are measurable or that are more than nominal in nature. We expressed concern about measures that merely reflected the status quo. Arrangements that merely drive nominal change or reflect only the status quo could be less likely to serve the care coordination aims of this rulemaking and more likely to be vehicles to reward referrals than arrangements in which parties receive remuneration designed to drive meaningful, more than nominal, change in patient care.

Accordingly, under the final rule, the outcome or process measures must include one or more benchmarks related to improvements in, or the maintenance of improvements in, the coordination and management of care for the target patient population. The measures must relate to the remuneration exchanged under the value-based arrangement so that there is a close nexus between the value-based activities under the arrangement and what the parties are measuring. Further, the measures cannot be based solely on patient satisfaction or patient convenience, both of which can be subjective, uninformative with respect to quality or efficiency of care, and gamed with relative ease, including through use of rewards or incentives to patients. On this last point, we are aware that some legitimate patient satisfaction or patient convenience measurement tools provide valuable information to providers and others managing patient care. This safe harbor does not preclude use of such tools (or any other form of measurement) as parties to value-based arrangements see fit and find useful. But patient satisfaction or patient convenience cannot be the only measure for purposes of satisfying the safe harbor. Lastly, we are finalizing a requirement for monitoring, periodically assessing, and prospectively revising an outcome or process measure and its benchmark, as necessary, as described below. This suite of requirements, taken together, is intended to reduce the likelihood of abuses and ensure that the selected measures relate to the protected remuneration and aim to foster meaningful advancements in the coordination and management of care.

Our revisions to the outcomes measure provision should address the concerns raised regarding measurement at the individual or group levels. This rule provides flexibility for parties to design legitimate measures appropriate to the arrangement, using internal or external data, and to account for characteristics such as available sample size and ability of individual physicians to effect change. It is up to the parties to determine which individual or entity that is a party to the arrangement, *e.g.,* a VBE participant, is accountable for assessing progress on measures.

We are not prescribing how many measures parties must use; while we anticipate value-based arrangements often would have more than one outcome or process measure (or measures that include process measures as a component of an outcome measure), some arrangements may lend themselves to only one measure. Additionally, we are not requiring that parties use only measures related to those outcomes or processes most important to patients or that value-based arrangements must, in fact, successfully advance the coordination and management of care for the target patient population. The standard we are finalizing is designed to encourage the selection of outcome and process measures that will result in improved care for patients. To the comment about the VBE's burden of proof in matters of dispute about the safe harbor, as with all safe harbors in the criminal Federal anti-kickback statute, any party seeking to avail themselves of the protection of a safe harbor generally bears the burden of proof that they meet the requirements of the safe harbor.

Comment: Some commenters expressed concern regarding whether parties must meet the outcome measures in order to have safe harbor protection, with a few commenters stating such a requirement would disadvantage providers treating higher-risk patient populations who may be less likely to meet outcome measures.

Response: We clarify that under the final rule, for purposes of this safe harbor, parties need not successfully achieve the outcome or process measure they select to qualify for safe harbor protection (and if they select more than one, they need not meet any of them). However, parties will need to monitor and periodically assess their arrangements and potentially revise measures and benchmarks, as described below. This will ensure that the selected measures remain a meaningful tool to advance care coordination goals. Without the requirement to establish and track progress toward achieving measures, the risk increases that parties could abuse the care coordination arrangements safe harbor to inappropriately drive referrals rather than patient care improvement.

We recognize that, despite best efforts, parties to a value-based arrangement may not always achieve their selected measures due to a variety of factors, such as uncertainty of patient behavior, lack of control of results by a VBE participant, or misjudgments.

We note a key distinction between this safe harbor and the protection of outcomes-based payments under the personal services and management contracts safe harbor. The personal services and management contracts safe harbor requires that agents achieve the outcome measure established for their payments in order to receive those payments. This is in keeping with a core purpose of the outcomes measure, which is to be the basis for a party to receive a protected outcomes-based payment.

Comment: A commenter supported adding a requirement for parties to make information regarding any outcome measures they establish transparent to the public.

Response: We are not requiring that the outcomes or process measures for value-based arrangements be made public under this safe harbor, although parties are free to do so. We did not propose a public transparency requirement and do not finalize one here. We recognize transparency serves important accountability and integrity goals. Consequently, we have included other conditions in the final safe harbor intended to foster transparency while balancing the potential burden on the parties seeking safe harbor protection. With respect to outcome or process measures, we are finalizing the requirement that parties include a description of the measures in a signed writing and make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of the care coordination arrangements safe harbor.

Comment: Several commenters stated that OIG should not require the use of

measures from CMS's Quality Payment Program (QPP) in the outcome measure requirement, arguing that existing QPP measures are inadequate for many specialties. Some commenters suggested OIG could encourage, but not require, participants to utilize the criteria for the QPP measures as a framework for establishing outcome measures. Alternatively, some commenters requested that OIG require the use of certain measures, such as measures promulgated by the National Quality Forum, or require all quality and cost measures to be independently assessed and approved by a third-party, multi-stakeholder organization.

Response: To provide flexibility and avoid triggering concerns that any specified measures may be inadequate or inappropriate for certain types of individuals or entities (*e.g.,* specialists), we are not requiring parties to utilize QPP measures or measures developed by any particular organizations or to receive third-party approval for the measures. Parties may use these measures at their discretion for purposes of this safe harbor.

Comment: Several commenters encouraged OIG to allow patient satisfaction and experience of care measures, such as timeliness of care, to qualify as outcome measures under the care coordination arrangements safe harbor. Along these same lines, a commenter suggested that OIG include patient satisfaction and efficiency of care measures, such as creating systems that prevent visits to the emergency room (for example, rapid outpatient testing and evaluation services) that would improve outcomes and reduce costs. This commenter observed that satisfied patients are more likely to keep follow up appointments and be compliant with care. Some commenters asserted that patient satisfaction and experience measures reflect quality of care and noted that CMS recognizes patient satisfaction as a quality measure that affects reimbursement. Other commenters supported using convenience measures, such as the availability of treatment times or timeliness of patient's access to care, as outcome measures because they asserted that patient adherence to treatment improves when care is convenient. Another commenter stated that, while convenience, alone, may not be a valid measure, OIG should permit parties to use convenience measures when they are tied to other measures, such as utilization. On the other hand, some commenters did not consider patient satisfaction or convenience to be a valid outcome measure, noting a lack of evidence tying patient satisfaction to better clinical outcomes.

Response: The commenters variously describe efficiency of care, patient satisfaction, patient convenience, and patient experience of care measures. As explained elsewhere, we have modified the outcomes measures requirement to include process measures, which addresses the commenters' suggestions regarding experience of care and efficiency of care measures, such as rapid access to outpatient testing and evaluation services. To assist commenters in appropriately categorizing their outcome or process measures, we provide additional clarification on patient satisfaction, patient convenience, and patient experience measures. For purposes of this rulemaking, patient satisfaction is about whether a patient's expectations for a health care encounter were met, *e.g.,* a patient's assessment of the responsiveness of hospital staff. Different patients with different expectations can experience the exact same care but report different degrees of satisfaction.[34] Patient convenience could include measures that assess patient access to care and accessibility of care, or the factors involved in arranging for the provision of care, *e.g.,* the distance or proximity to a site of care or the hours during which care can be obtained.

In applying our regulation, patient experience can involve finding out whether something that should happen in a health care setting happened, for example, whether all hospital discharge planning protocols were followed for certain patients. Patient experience measures can overlap with patient satisfaction or convenience measures; in particular, patient satisfaction or patient convenience could be a sub-part of a patient experience measure. Accordingly, whereas patient satisfaction or patient convenience cannot be the sole measure for purposes of the care coordination arrangements safe harbor, the same may not be true for patient experience measures, depending on the facts and circumstances.

As stated in the OIG Proposed Rule, we are concerned that patient satisfaction and patient convenience measures may not reflect actual improvement in the quality of patient care, health outcomes, or efficiency in the delivery of care. In some cases, such measures can be subjective, uninformative with respect to quality or efficiency of care, and potentially gamed with relative ease, including through use of rewards or incentives to patients. That said, some patient satisfaction or patient convenience measurement tools provide valuable information to government programs, providers, and others managing patient care. This safe harbor does not preclude use of such tools (or any other form of measurement) as parties to value-based arrangements see fit and find useful. As noted previously, while patient satisfaction or patient convenience cannot be the sole measure for purposes of the care coordination arrangements safe harbor, patient satisfaction or patient convenience can be tied to other legitimate measures or can exist alongside such other measures.

Comment: Several commenters encouraged OIG not to require regular rebasing of outcome measures, and in particular, they opposed specific timing for when parties must rebase these measures. These commenters asserted that any timing requirement would be arbitrary, might discourage participation in value-based arrangements, or may not be clinically appropriate in all circumstances. A commenter expressed concern that requiring rebased outcome measures could lead to the unintended consequence of providers abandoning proven care coordination programs once they have achieved a maximized performance level. On the other hand, some commenters supported this requirement; for example, a commenter supported rebasing pursuant to a specified timeframe, such as every year, as long as the VBE participants determined that rebasing is feasible.

Response: In the OIG Proposed Rule, we considered whether to require parties to rebase outcomes measures (*i.e.,* reset benchmarks used to determine whether the outcome measure was achieved) where rebasing is feasible. We indicated our intent to consider specifying a timeline for rebasing or requiring that it be done periodically. We solicited comments on whether rebasing should depend on the type of outcome measure or the nature of the arrangement. We also explained in the preamble to the OIG Proposed Rule that revisions to outcomes measures (*i.e.,* modification of outcomes measures) would need to continue to incentivize the recipient of the remuneration to make meaningful improvements. We expressed concern that retrospective revisions could obscure a lack of meaningful improvement.

Upon further consideration of the terminology in the OIG Proposed Rule, we conclude that we can best express our intended policy by using the term ''revise'' rather than ''rebase'' in the final rule. The term ''revise'' has a broader common meaning and better reflects the goal that measures be

changed or updated to advance improvements in care coordination. In addition, we view ''rebase'' as a subcategory of ''revise''; in other words, we recognize that the rebasing of benchmarks may be the best way to ''revise'' the measure. Because we intended for parties to have the flexibility to either ''revise'' measures, *i.e.,* modify or update measures to advance improvements in care coordination, or ''rebase'' benchmarks, and because ''revise'' could serve as an umbrella term which would include ''rebase,'' we believe ''revise'' encapsulates our intent.

In practice, parties can meet the requirement by revising the measure itself or by rebasing the benchmarks for the measure. We recognize that rebasing may not be necessary for all legitimate outcome or process measures that advance the coordination and management of care for a target patient population. For the final rule, measures must be monitored, periodically assessed, and prospectively revised as necessary to ensure that the measure and its benchmark continues to advance the coordination and management of care of the target patient population. We emphasize that any revisions must be prospective, not retrospective.

We are requiring a periodic assessment and, as necessary based on such assessment, revision of outcome or process measures and benchmarks. Recognizing that different measures should be assessed on different timelines, we are not implementing a specific timeframe for assessing or revising measures, as in some cases, outcome measures could be reviewed annually, whereas for others significant benefits to patients could reasonably take 2 to 3 years to achieve.

As evidenced by the above discussion, we are also finalizing a requirement for parties to a care coordination arrangement to have one or more benchmarks for each outcome or process measure that are related to improving or maintaining improvements in the coordination and management of care of the target patient population. Benchmarks help ensure that the remuneration exchanged pursuant to the value-based arrangement continues to drive meaningful improvements, or the maintenance of improvements, in the coordination and management of care for the target patient population.

Comment: Some commenters opposed a requirement for payors to identify outcome measures, positing that such a top-down approach would limit providers that are best situated to identify value-driving activities and may be impractical when payors are not parties to a value-based arrangement. Another commenter suggested that the adoption of payor-identified outcome measures by a VBE should be a favorable factor when evaluating a value-based arrangement for compliance with the proposed safe harbor. According to the commenter, payors have unique capabilities to: (i) Give providers the information they need to identify patient populations that may benefit most from management and care coordination interventions; and (ii) recommend benchmarks based on experience and access to data that are used to assess outcome measures.

Response: The final rule allows, but does not require, the use of payor-driven or developed outcome measures. Parties are free to use payor measures if they find them useful or if doing so is required by a payor.

Comment: We solicited comments on using a different outcomes measures standard for information technology than for other care coordination arrangements. Commenters were generally supportive of an alternative standard, such as an adoption and use standard, stating that it would allow more flexibility, which is important for arrangements that are centered on an ever-changing and developing industry. At least one commenter suggested language for this alternative standard, namely, ''the parties determine in good faith that the technology is expected to meaningfully advance achievement of the targeted health outcomes, patient care quality improvements, or the appropriate reduction in costs . . . [etc.],'' while another commenter suggested that VBE participants should have the option, but not be required, to designate utilization and adoption measures in IT arrangements as alternatives to outcome measures. A commenter who supported the use of alternative measures for IT advocated against OIG's proposal to implement a time frame after which the recipient of IT would be required to pay fair market value for continued use of the IT, stating that suddenly requiring fair market value payments may unnecessarily cause drastic and costly changes to an entire system and could disrupt continuity of care.

Response: The final rule for establishing the required outcomes or process measures is flexible enough to address information technology arrangements. Legitimate process measures (including use and adoption) or performance measures can be used so long as the parties reasonably anticipate that the measures will advance the coordination and management of care of the target patient population and the benchmark and other requirements are met. No separate outcome measures requirement is needed for information technology arrangements. We are not finalizing our proposal that outcomes measures be evidence-based, which we acknowledged could have been a difficult standard for some information technology arrangements. Measures must be selected based on clinical evidence or credible medical or health science support. This support may be based on external sources or generated internally. The specific addition of health science as a basis for selection reflects our intent, among other things, to allow remuneration in the form of information technology under the care coordination safe harbor. Since we are not including an IT-specific standard, we are not placing a time limit on the use of IT-related remuneration in care coordination arrangements. In light of our modifications to the measurement standard and other safeguards against fraud and abuse in the safe harbor, adopting the additional requirements we considered in the OIG Proposed Rule related to outcomes measures for the exchange of health information technology is not necessary.

c. Commercial Reasonableness

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ee)(2) to require that the value-based arrangement pursuant to which the remuneration is exchanged be commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE. We indicated that we were considering for the final rule whether to define a ''commercially reasonable arrangement'' as an arrangement that would make commercial sense if entered into by reasonable entities of a similar type and size, even without the potential for referrals. We solicited comments on the need for a definition of a ''commercially reasonable arrangement.''

Summary of Final Rule: We are finalizing, without modification, our proposed requirement at paragraph 1001.952(ee)(2). We are not defining a ''commercially reasonable arrangement'' in the final rule.

Comment: Some commenters supported a commercial reasonableness requirement while others opposed it. Several commenters noted that this requirement is inconsistent with the value-based arrangements exception to the physician self-referral law, which does not require that the value-based arrangement be commercially reasonable. Others emphasized that the

standard introduces complexity and uncertainty that may require parties to consult with legal counsel, with some of these commenters asserting that this burden could have a disproportionate impact on small and rural providers.

Response: In the context of care coordination arrangements where parties are not required to take on financial risk, the remuneration does not need to be consistent with fair market value, and the remuneration may take into account the volume of patients in the target patient population or the value of referrals or other business generated between the parties resulting from referrals of the target patient population, we believe requiring the value-based arrangement to be commercially reasonable is an important safeguard to ensure that safe harbor protection is limited to remuneration exchanged pursuant to value-based arrangements that are designed and implemented to achieve legitimate objectives rather than merely to induce or reward referrals.

The commercial reasonableness requirement focuses on ensuring that parties structure the terms of their value-based arrangement, including but not limited to the amount of the remuneration, in a manner that is calibrated to achieve the parties' legitimate business purposes. For example, as described in the OIG Proposed Rule, if VBE participants were to enter into a value-based arrangement to facilitate the sharing of patient-outcome data, it may be commercially reasonable for a hospital VBE participant to donate technology to a group practice VBE participant to facilitate this process. However, it may not be commercially reasonable for that same hospital VBE participant to donate technology substantially more sophisticated, or with enhanced functionality, beyond that necessary for communicating data on shared patients between the two parties.[35] We are concerned that, absent the commercial reasonableness requirement, the other conditions in this safe harbor will not sufficiently mitigate the risk of one party offering more remuneration than is necessary, such as in the example above, to reward the other party for referrals of target patient population patients, which is why we are finalizing the requirement in this final rule that the value-based arrangement itself be commercially reasonable. Further, the commercial reasonableness requirement is the only safeguard in the care coordination arrangements safe harbor that directly addresses the risk that parties might use a series of value-based arrangements to effectuate a payment-for-referral scheme. For this reason, we are finalizing the second prong of the commercial reasonableness requirement that the value-based arrangement must be commercially reasonable when considering all value-based arrangements in the VBE.

In sum, the commercial reasonableness requirement in this safe harbor: (i) Helps to ensure that the value-based arrangement, and all value-based arrangements within in the VBE, serve legitimate objectives; (ii) mandates that parties structure the terms of their value-based arrangement, including but not limited to the amount of the remuneration, in a manner that is calibrated to achieve the parties' legitimate business purposes; and (iii) reduces the likelihood that the value-based arrangement might be a payment-for-referral scheme.

With respect to the complexities associated with assessing commercial reasonableness and the potential need to consult with legal counsel, we appreciate those concerns and note that the inclusion of a commercial reasonableness condition in safe harbors is not new. Several existing safe harbors require protected remuneration to be commercially reasonable. We believe parties, including small and rural providers, can apply this concept and that including it as a condition of this safe harbor will not impose significant additional burden.

In response to those commenters who noted that the proposed safe harbor is inconsistent with CMS's proposed exception for value-based arrangements, we note that CMS's exception for value-based arrangements (42 CFR 411.357(aa)(3)), as finalized, includes a commercial reasonableness requirement.

Comment: A commenter asserted that the move to value-based care helps to eliminate many of the program integrity concerns that OIG might seek to address through a commercial reasonableness requirement.

Response: We agree that a shift to value-based payment models may curb some of the traditional program integrity concerns associated with a fee-for-service payment system. However, this safe harbor offers protection for care coordination arrangements without requiring that the parties assume financial risk or otherwise participate in a value-based payment model. As a result, the traditional program integrity risks resulting from fee-for-service payment are likely to persist. For example, we are concerned that, in some circumstances and in the absence of safe harbor guardrails, remuneration furnished pursuant to a value-based arrangement may lead to overutilization, corruption of practitioners' medical judgment, inappropriate patient steering, or unfair competition. By requiring the value-based arrangement to be commercially reasonable with respect to both the arrangement itself and all value-based arrangements within the VBE, this condition helps to safeguard against these program integrity concerns by requiring that the terms of the value-based arrangement be calibrated to achieve the parties' legitimate business purposes.

For example, we explained in the OIG Proposed Rule that a single value-based arrangement in which a hospital VBE participant provides a necessary number of care coordinators for the target patient population to a SNF VBE participant may be commercially reasonable. However, if a VBE includes multiple similar value-based arrangements, each of which involves the same hospital VBE participant furnishing care coordinators to the same SNF VBE participant for the same or a similar target patient population, the commercial reasonableness of the remuneration exchanged within the value-based arrangements in the aggregate may be suspect if it lacks a legitimate business purpose.[36] This arrangement could lead to the program integrity concerns identified above (*e.g.,* inappropriate patient steering) and, absent a commercial reasonableness requirement, the conditions of the safe harbor might otherwise be met.

Comment: Some commenters asserted that a commercial reasonableness requirement will create an obstacle to value-based care. Others asserted that few arrangements would ever satisfy this criterion because value-based arrangements do not make any commercial sense without the potential for referrals. These commenters noted that changes in referral patterns alone are not the goal of a value-based arrangement but that they may well be the consequence.

Response: We are not persuaded that a commercial reasonableness requirement will impede the transition to value-based care. We believe that it is eminently feasible to structure value-based arrangements to meet the commercial reasonableness requirement by ensuring that the terms of the value-

[35] 84 FR 55709. In the OIG Proposed Rule, we noted in connection with this example that nothing would prevent the donation of technology with enhanced functionality when a value-based arrangement requires that capability or when technology without that functionality is not practicable.

[36] 84 FR 55709.

based arrangement, and all value-based arrangements within the VBE, are reasonably calculated to achieve the VBE participants' legitimate business purposes.

The framing of the commercial reasonableness condition in the final rule, which allows for the possibility of referrals, addresses the commenters' concerns. Specifically, we recognize that a value-based arrangement may, and often will, result in referrals. The commercial reasonableness requirement is intended to ensure that the terms of the value-based arrangement, considering both the arrangement itself and all value-based arrangements within the VBE, are calibrated to achieve the value-based purpose(s) of the arrangement, not the generation of referrals. We agree with the commenters' related assertion that changes in referral patterns alone are not the goal of a value-based arrangement but may be the consequence.

For example, a value-based arrangement that provides remuneration in excess of what is reasonably necessary to coordinate and manage the care of the target patient population, as contemplated by the terms of that arrangement, would not be commercially reasonable. Likewise, terms that are calibrated to secure referrals, rather than to achieve the value-based purposes of the value-based arrangement, would result in an arrangement that is not commercially reasonable for purposes of this safe harbor. The mere fact that referral patterns may change as a result of a value-based arrangement does not necessarily preclude the arrangement from meeting the commercial reasonableness requirement.

Comment: With respect to whether we should adopt a definition for a commercially reasonable arrangement, several commenters expressed support, but these commenters did not agree on a definition. Some commenters supported the definition presented in the preamble to the OIG Proposed Rule, which defined a ''commercially reasonable arrangement'' as an arrangement that would make commercial sense if entered into by reasonable entities of a similar type and size, even without the potential for referrals. Others encouraged us to adopt CMS's proposed definition, which states that commercially reasonable means the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. Other commenters suggested that OIG should focus on whether the arrangement makes ''value-based'' sense in the context of a value-based arrangement instead of whether it makes ''commercial'' sense. Other commenters provided alternative definitions that varied in scope. A commenter asserted that the definition should not preclude consideration of referrals not covered by Medicare.

Commenters also requested various clarifications and affirmative statements from OIG, including that: (i) Commercial reasonableness refers primarily to the non-financial elements of a transaction or arrangement while the concept of fair market value addresses the financial aspects, and (ii) an arrangement may be commercially reasonable even if it operates at a loss.

Response: While we are not adopting a definition of ''commercially reasonable arrangement,'' we appreciate commenters' requests for guidance. There are multiple dimensions to commercial reasonableness, including both the financial and non-financial terms of an arrangement. The fact that an arrangement generates a loss for a party is one factor, among many, that could be considered in analyzing whether an arrangement is commercially reasonable. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties. Any determination whether a particular value-based arrangement is commercially reasonable would be based on the totality of the facts and circumstances of such arrangement, and the financial aspects of the value-based arrangement would be relevant to that inquiry.

With respect to the assertion that the commercial reasonableness definition should not preclude consideration of referrals of non-Medicare business, as we stated above, we are not adopting this definition. We reiterate that the commercial reasonableness requirement in this safe harbor requires that the VBE participants structure the terms of the value-based arrangement in a manner that is calibrated to achieve the parties' legitimate business purposes. We also reiterate our longstanding guidance that arrangements that do not involve referrals of Federal health care program beneficiaries or business generated by Federal health care programs may implicate the Federal anti-kickback statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business. Arrangements with this type of disguised remuneration would not be calibrated to achieve a legitimate business purpose and would thus not be commercially reasonable. Whether any particular arrangement reflects this type of disguised remuneration would depend on the specific facts of the arrangement.

Comment: Some commenters asserted that the definition of ''commercially reasonable arrangement'' in the preamble to the OIG Proposed Rule, which considered defining such an arrangement as one that would make commercial sense if entered into by reasonable entities of a similar type and size, even without the potential for referrals, is inconsistent with OIG's prior commentary relating to the requirement in certain other safe harbors that the remuneration must be reasonably necessary to accomplish the commercially reasonable business purpose of the arrangement.

Response: We are not further defining a ''commercially reasonable arrangement'' in this final rule, beyond the test for commercial reasonableness articulated in the regulatory text (*i.e.,* that commercial reasonableness must be evaluated by considering both the value-based arrangement itself and all value-based arrangements within the VBE). As explained above, the test for commercial reasonableness is tailored to this particular safe harbor for care coordination arrangements and is meant to be both flexible to allow for innovative arrangements that serve legitimate objectives and sufficiently constrained to limit the risk of schemes to pay for referrals. That said, our prior guidance remains instructive on the application of the term ''commercially reasonable'' in the safe harbor context, particularly with respect to having a legitimate business purpose.[37]

d. Writing

Summary of OIG Proposed Rule: We proposed in proposed paragraph 1001.952(ee)(3) to require that each value-based arrangement, pursuant to which the remuneration is exchanged, be set forth in a signed writing, established in advance of, or contemporaneous with, the commencement of the value-based arrangement or any material change to the value-based arrangement. We proposed in the same paragraph that the writing state, at a minimum: (i) The value-based activities to be undertaken

[37] *See, e.g.,* Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule, 64 FR 63518, 63425 (Nov. 19, 1999) *available at https://oig.hhs.gov/fraud/docs/safeharborregulations/getdoc1.pdf.*

by the parties to the value-based arrangement; (ii) the term of the value-based arrangement; (iii) the target patient population; (iv) a description of the remuneration; (v) the offeror's cost for the remuneration; (vi) the percentage of the offeror's cost contributed by the recipient; (vii) if applicable, the frequency of the recipient's contribution payments for the offeror's ongoing costs; and (viii) the specific evidence-based, valid outcome measure(s) against which the recipient would be measured.

Summary of Final Rule: We are finalizing, with modifications, the writing requirement in paragraph 1001.952(ee)(3). The following modifications respond to public comments: (i) The writing requirement can be satisfied by a collection of documents; (ii) parties must document the fair market value of the remuneration or, alternatively, the offeror's cost of the remuneration and the accounting methodology utilized to determine such cost; and (iii) parties must document the value-based purpose(s) of the value-based activities provided for in the value-based arrangement. We are also clarifying that the terms of the value-based arrangement must be established in advance of, or contemporaneous with, the commencement of the value-based arrangement ''*and* any material change,'' instead of ''*or* any material change.'' In the preamble to OIG Proposed Rule, we described a writing requirement that would promote transparency of the value-based arrangement, both at its commencement and when there is a material change. These are the logical junctures where the writing requirement particularly serves its transparency purposes. Our proposed regulatory text did not make clear that the writing was needed at both junctures; our modifications more clearly express that policy. Lastly, we are modifying the writing requirement for consistency with changes to the language of the outcome and process measures condition, discussed in section III.3.b. The remaining requirements of the writing requirement are finalized as proposed.

Comment: While several commenters expressed support for the writing requirement, numerous commenters were concerned that this requirement does not afford parties the flexibility to document their value-based arrangement in a ''collection of documents'' and instead requires a single signed writing.

Response: We have revised the writing requirement to permit a ''collection of documents'' approach in response to commenters' concerns. To receive safe harbor protection, the terms of the value-based arrangement must be set forth in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the value-based arrangement and any material change to the value-based arrangement. Under this approach, parties are not required to have a single, signed writing setting forth the terms of the agreement, but there must be either a single, signed writing or a collection of documents in place—in advance of, or contemporaneous with, the commencement of the value-based arrangement—in order to meet this condition. In addition, if any material term (*e.g.,* an outcome or process measure) changes during the course of the value-based arrangement, the parties would need to set forth such changes in a signed writing or collection of documents in advance of, or contemporaneous with, the commencement of the modified value-based arrangement. We note that, while the terms do not need to be set forth in a single, signed writing, we believe this approach is a best practice from a compliance perspective.

Comment: A commenter requested that OIG permit a VBE to sign the writing required by this safe harbor on behalf of all parties to the applicable value-based arrangement because, according to the commenter, it would be challenging to arrange for all parties to sign a single document in advance of the commencement of the value-based arrangement.

Response: We decline to adopt the commenter's suggestion. To promote transparency and accountability, each value-based arrangement must be set forth in writing and signed by all parties to the value-based arrangement. While the VBE may be a signatory to the value-based arrangement, its signature alone would not meet the writing requirement for this or any of the other value-based safe harbors. We believe there is sufficient flexibility in this requirement insofar as we do not require the writing to be a single document (*i.e.,* the parties can sign separate documents), and we allow it to be signed in advance of, or contemporaneous with, the commencement of the value-based arrangement.

Comment: Some commenters disagreed with the proposed writing requirement, stating that it was burdensome, was too prescriptive, or would increase the risk of inadvertent non-compliance. Commenters took particular issue with the requirement that parties document the offeror's cost for the remuneration. A commenter asserted that this provision is unnecessary in light of the condition to maintain and make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this safe harbor, while at least two commenters expressed concern that it could result in the inappropriate disclosure of competitively sensitive information. One such commenter provided the example of an offeror that might furnish certain in-kind remuneration to a VBE participant to benefit the VBE and further its value-based purpose, but who might want to offer the same in-kind remuneration to the recipient at market rates for use in other lines of business. According to the commenter, it would be commercially unreasonable to require the offeror to disclose its cost structure and requested that we allow parties to satisfy this condition through a written representation that the contribution amount equals at least 15 percent of the offeror's cost.

Response: We are not persuaded that our writing requirement is overly prescriptive or burdensome, rather it is an essential safeguard. The required contents are of the kind commonly part of business agreements: The parties, purposes, services, financial and business terms, duration, and metrics. In addition, for safe harbor purposes, we view the requirement that the writing set forth the offeror's cost for the remuneration or the fair market value of the remuneration—detailed in section III.B.3.g—as a material term to the parties' arrangement because of the safe harbor's 15 percent contribution requirement. The inclusion of this term in the writing ensures a transparent understanding of the arrangement agreed to by the parties.

Accordingly, we are finalizing the writing requirement, including a requirement that parties document: (i) Either the fair market value of the remuneration or the offeror's cost of the remuneration, dependent upon the methodology used by the parties to determine the contribution amount; and (ii) the percentage and amount contributed by the recipient. Consistent with revisions to the contribution requirement methodology discussed in detail in section III.B.3.g, we require that parties who choose to document the offeror's cost of the remuneration, instead of the fair market value, also must document the reasonable accounting methodology used to calculate such costs.

We believe requiring parties to calculate and document the contribution amount based on the fair

market value of the remuneration or the offeror's cost of the remuneration addresses commenters' confidentiality concerns and, for this reason, we are not adopting the commenter's suggestion to use written representations of the offeror's cost for the purposes of satisfying the writing requirement. We understand that information relating to an offeror's cost may include proprietary or competitively sensitive information that parties might not wish to put in their written agreements. We do not believe the same holds true for fair market value.

In response to commenters' concerns that the writing requirement increases the risk of inadvertent non-compliance, we note that our modification to permit a collection of documents to satisfy the requirement should help address compliance concerns by incorporating more flexibility in this requirement. Further, should an arrangement inadvertently fail to comply with a safe harbor condition that would not mean that the arrangement violates the Federal anti-kickback statute. Rather, the arrangement would not have safe harbor protection and would need to be analyzed based on its facts, including the intent of the parties, for compliance with the statute.

Comment: A commenter requested that we address how parties to a value-based arrangement would need to document a value-based arrangement's value-based purpose.

Response: We did not expressly propose—as part of the writing requirement—that the parties document the value-based purpose(s) of the value-based activities provided for in the value-based arrangement. However, such requirement, which we are including in the final rule, effectuates our intent and logically flows from the intersection of the following proposals, each which is finalized here: (i) That the writing state, among other things, the value-based activities to be undertaken by the parties to the value-based arrangement; (ii) the ''value-based activity'' definition, which would require, in part, that the activity is reasonably designed to achieve *at least one value-based purpose of the value-based enterprise;* and (iii) the requirement that protected remuneration be used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. In particular, it seems sensible that in describing the value-based activity—which, by definition, are reasonably designed to achieve *at least one value-based purpose of the value-based* enterprise—and to confirm that one purpose is the coordination and management of care, the writing would specify the value-based purpose that the activities are designed to achieve.

Consequently, we finalize a condition requiring that parties document the value-based purpose(s) of the value-based activities provided for in the value-based arrangement as part of the required writing. In particular, we view the documentation of the value-based purpose(s)—and specifically, documentation of the care coordination and management of care purpose—to be an important component of a writing designed to ensure transparency and accountability.

e. Limitations on Remuneration

i. In-Kind Remuneration

Summary of OIG Proposed Rule: We proposed that the remuneration exchanged must be in-kind under the proposed condition at paragraph 1001.952(ee)(4)(i).

Summary of Final Rule: We are finalizing, without modification, the requirement that the remuneration be in-kind, and moving it to paragraph 1001.952(ee)(1)(i).

Comment: While some commenters supported limiting protection under the care coordination arrangements safe harbor to in-kind remuneration, a number of commenters requested that OIG expand the safe harbor to protect monetary remuneration of any amount or, alternatively, monetary remuneration up to a certain amount annually. Many commenters asserted that the proposed safe harbor would not protect financial arrangements that incentivize behavior change, such as shared savings payments or payments to adhere to care protocols, and further asserted that the other safeguards in the safe harbor are sufficient to protect against fraud and abuse. A commenter suggested that OIG only protect shared savings distributed after the VBE has satisfied its expenses. Some commenters requested that the safe harbor protect monetary remuneration distributed under upside-only risk arrangements, particularly where the remuneration is tied directly or indirectly to achievement under a value-based arrangement with a payor. Other commenters asserted that the care coordination arrangements safe harbor should protect ownership, investment interests, loan arrangements (including interest payments), and similar transactions to fund infrastructure for the VBE that will facilitate the development and operation of a value-based arrangement.

Other commenters asserted that the safe harbor should permit the exchange of monetary remuneration, so physician practices can receive remuneration and purchase their own clinical tools or services and select staff members who best meet the needs of the practice. For example, a primary care practice explained that it would like to engage a psychologist or behavioral health professional to assist with patients presenting with depressive symptoms or needing additional assistance managing mental health conditions and that expanding this safe harbor to protect monetary remuneration would allow the practice to select a behavioral health professional who, among other things, best meets the needs of the practice's patient population. They explained that, otherwise, the offeror of in-kind remuneration would make those purchasing decisions and selections for the recipient. Another commenter asserted that OIG's and CMS's final rules should align to protect both in-kind and monetary remuneration or only in-kind remuneration, arguing that any inconsistency would result in a barrier to the advancement of value-based care. A commenter suggested that the safe harbor protect monetary remuneration for specific services; for example, a hospital might offer to cover the costs of a nurse navigator at a SNF, instead of providing the nurse navigator directly, because it wants the SNF to have the contractual relationship with the nurse navigator. Lastly, several commenters requested that OIG expand the safe harbor to protect monetary remuneration exchanged under arrangements involving Indian health programs.

Response: We are finalizing the requirement that the remuneration exchanged pursuant to this safe harbor must be in-kind. We continue to believe that providing safe harbor protection to monetary remuneration exchanged under arrangements where: (i) The parties are not required to assume financial risk, and (ii) the protected remuneration is not required to be fair market value and may take into account the volume or value of referrals for the target patient population, presents heightened fraud and abuse risks that outweigh the potential benefits to Federal health care programs and patients. OIG's longstanding guidance makes clear that remuneration in the form of cash and cash equivalents pose a higher risk of interfering with clinical decision-making, incentivizing overutilization or inappropriate utilization, and increasing costs to Federal health care programs. We do not

view protection for ownership or investment interests as fundamental to parties entering into value-based arrangements for the coordination and management of care for a target patient population. Parties seeking to protect a particular investment interest may look to existing safe harbors (*e.g.,* the safe harbor for investment interests at paragraph 1001.952(a)); in addition, the advisory opinion process remains available. Further, while we understand recipients' desire to select their own care coordination items and services rather than receiving items and services an offeror selects, we note that parties do not have to enter into value-based arrangements and might agree to enter into such arrangements only where the item(s) or service(s) being offered are satisfactory to the recipient. We also note that, where a party offering remuneration desires for the recipient to contract directly for items and services, the recipient may do so as long as the offeror pays the vendor of the items and services directly. Further, while we understand recipients' desire to select their own care coordination items and services rather than receiving items and services an offeror selects, we note that parties do not have to enter into value-based arrangements and might agree to enter into such arrangements only where the item(s) or service(s) being offered are satisfactory to the recipient. We also note that, where a party offering remuneration desires for the recipient to contract directly for items and services, the recipient may do so as long as the offeror pays the vendor of the items and services directly. Lastly, we note that individuals and entities may look to other safe harbors, such as the safe harbor for personal services and management contracts and outcomes-based payment arrangements at paragraph 1001.952(d), for protection for certain monetary remuneration.

Finally, in response to the comment requesting that CMS's and OIG's final protections align to protect both in-kind and monetary remuneration or only in-kind remuneration, we refer readers to section III.A.1, where we discuss fundamental differences in statutory structures and sanctions across the physician self-referral law and Federal anti-kickback statute and elaborate on the reasoning behind conditions that differ in any similar exception and safe harbor finalized by CMS and OIG, respectively, in each agency's final rule in connection with the Regulatory Sprint. With respect to OIG's specific policy to limit the care coordination arrangements safe harbor to in-kind remuneration, this policy addresses the heightened risk that fungible monetary remuneration could be misused to make intentional kickback payments and would be more difficult to track. OIG and CMS permit monetary and non-monetary remuneration in the value-based safe harbors and exceptions that require parties to assume risk.

ii. Remuneration Used To Engage in Value-Based Activities

Summary of OIG Proposed Rule: We proposed to require, at proposed paragraph 1001.952(ee)(4)(ii), that the remuneration provided by, or shared among, VBE participants be used primarily to engage in value-based activities that are directly connected to the coordination and management of care of the target patient population. We recognized that in-kind remuneration exchanged for value-based activities may indirectly benefit patients outside of the scope of the value-based arrangement and that parties may find it difficult to anticipate or project the scope or extent of these ''spillover'' benefits.

Summary of Final Rule: We are finalizing, with modifications, the proposed requirement at paragraph 1001.952(ee)(1)(ii). The two modifications are explained in greater detail in the responses to comments. First, the remuneration exchanged must be used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. We replaced the word ''primarily'' with the word ''predominantly.'' Second, we added a condition that the remuneration exchanged result in no more than incidental benefits to persons outside of the target patient population. Further, for the reasons previously explained in the value-based terminology section discussing the definition of the ''coordination and management of care'' at section III.B.2.g, we added a condition to this final safe harbor clarifying that remuneration exchanged pursuant to a value-based arrangement may not be exchanged or used more than incidentally by the recipient for the recipient's billing or financial management services.

Comment: Commenters generally supported our proposal to require that protected remuneration be primarily used to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population and expressed concerns about our alternative proposal to require that the remuneration exchanged be limited to value-based activities that only benefit the target patient population. Commenters asserted a variety of reasons why prohibiting spillover benefits outside the target patient population would be unworkable or undesirable in practice. For example, some commenters asserted that prohibiting spillover benefits would create a disincentive for innovation, and others emphasized the complexities in trying to manage benefits to prevent spillover. Some commenters requested that we expressly state that the benefits of the value-based arrangement do not need to be limited to the members of a target patient population. Another commenter stated that the term ''primarily'' is vague, which could make this requirement difficult to implement and monitor.

Response: We agree with the commenters' concerns that prohibiting spillover benefits outside of the target patient population would be unworkable. In the OIG Proposed Rule, and for purposes of this final rule, we recognize that in-kind remuneration exchanged for value-based activities may indirectly benefit patients out of the scope of the associated value-based arrangement and that parties may find it difficult to anticipate or project the extent of such ''spillover'' benefits. We likewise acknowledge the need to provide parties with sufficient flexibility while also minimizing the risk of disguised, improper remuneration unrelated to the coordination and management of care for the target patient population. To address the commenters' concerns about spillover effects, in the final rule we have clarified that the value-based activities for which the remuneration is used can result in no more than incidental benefits to persons outside of the target patient population. This language acknowledges the difficulty VBE participants could face in preventing ''spillover'' benefits and reflects our intent to permit safe harbor protection for care coordination arrangements that predominantly benefit the target patient population.

We are replacing the proposed term ''primarily'' with ''predominantly'' in the final rule. These words are analogous (*e.g.,* meaning chiefly, mainly, principally). We make the change for consistency with comparable language in other safe harbors. The term ''predominantly'' appears for a similar purpose in the EHR and cybersecurity safe harbors, at paragraphs 1001.952(y) and (jj), respectively, and our parallel use of the same term in paragraph 1001.952(ee) enhances consistency for stakeholders across safe harbors. To the commenter's concern about vagueness,

we are not quantifying with specificity the degree to which remuneration is used to engage in value-based activities to offer flexibility for the range of value-based arrangements for which safe harbor protection may be sought.

Comment: Several commenters requested that we clarify that a device with multiple functions does not violate the Federal anti-kickback statute or the Beneficiary Inducements CMP when it is primarily used for managing a patient's health care. Commenters noted that increasingly medical devices are being produced with multiple functions, or they rely on non-medical platforms such as consumer electronic products (*e.g.,* smartphones, tablets).

Response: It appears that the commenters are asking whether the furnishing of a multi-function device, or a device that relies on a multi-use technology platform, can meet the safe harbor requirement that the remuneration is predominantly used to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. We also presume for purposes of this response that the device would be furnished to the recipient for less than fair market value.

As a threshold matter, compliance with the care coordination arrangements safe harbor depends on whether the device is furnished from one VBE participant to another VBE participant or if the device is furnished directly from a VBE participant to a patient. If the device is furnished by a VBE participant to another VBE participant, then the care coordination arrangements safe harbor may protect the remuneration if the device will be used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population, and all other safe harbor requirements are met.

For example, a health information technology tool that enables both remote patient monitoring and two-way telehealth capabilities may satisfy the predominant use requirement if the remote patient monitoring and two-way telehealth technologies will be used by the recipient to coordinate and manage care for the target patient population. However, a health information technology tool that includes some functionalities that the recipient may use to coordinate and manage care for the target patient population and other functionalities that the recipient may use for purposes other than to coordinate and manage care for the target patient population may not meet this standard. For example, a health information technology tool that the recipient VBE participant uses to collect, track, and analyze data relevant to the outcome measures established by the VBE participants and is also used to collect, track, and analyze the VBE participant's internal financial metrics for purpose of operating its own business would likely not meet the predominant use standard, unless the use for financial metrics is minimal.

In the above example, if the VBE participants wish to protect the health information technology tool under this safe harbor, the financial monitoring functionalities could be disabled to ensure that the predominant use test is met. Alternatively, if the recipient VBE participant pays fair market value for the financial monitoring functionalities, then the parties might conclude that they do not need to protect that aspect of the arrangement under this safe harbor, or they may look to another safe harbor, such as the personal services and management contracts safe harbor at paragraph 1001.952(d), to protect that aspect of the arrangement. To be protected under paragraph 1001.952(ee), the remaining remuneration for which fair market value has not been paid would need to meet the predominant use condition and all other safe harbor conditions.

We note that if the collecting, tracking, and analyzing data for the outcomes measures for the target patient population results in the VBE participant observing something that prompts a change to how it delivers care for all patients, not just the target patient population, this additional use would constitute an incidental benefit to persons outside the target patient population; such incidental benefit would not be a disqualifying feature of the remuneration under this provision in paragraph 1001.952(ee).

If a multi-function device is being furnished by a VBE participant directly to a patient, then the VBE participant would look to the patient engagement and support safe harbor, at paragraph 1001.952(hh), for protection, not the care coordination arrangements safe harbor. As explained above, the care coordination arrangements safe harbor does not protect remuneration—including a free or discounted device—flowing from VBE participants to patients. Note that, among other requirements, the patient engagement and support safe harbor requires that the remuneration has a direct connection to the coordination and management of care of the target patient population.

With respect to the Beneficiary Inducements CMP, we note that remuneration that is protected under a safe harbor to the Federal anti-kickback statute is not considered remuneration for purposes of the Beneficiary Inducements CMP.

Comment: Some commenters argued that this proposed limitation on the exchange of remuneration—in particular, the requirement that the remuneration be used to engage in value-based activities directly connected to the *coordination and management of care* of the target patient population—is unduly restrictive. Commenters stated that this condition should not be limited to the first of the four value-based purposes (the coordination and management of care for the target patient population) and should be expanded to permit a direct connection to any of the value-based purposes. Commenters further asserted that expanding this condition to require a direct connection to any value-based purpose would reduce regulatory burden, foster innovation, and facilitate alignment with CMS's value-based exceptions to the physician self-referral law.

Response: The care coordination arrangements safe harbor does not preclude a value-based arrangement from furthering other value-based purposes; however, the safe harbor does require that the remuneration exchanged be used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. By requiring that each party to a value-based arrangement under the care coordination arrangements safe harbor include the coordination and management of care for the target patient population as at least one of the value-based purposes, we seek to distinguish between referral arrangements, which would not be protected, and legitimate care coordination arrangements, which naturally involve referrals across provider settings but include beneficial activities beyond the mere referral of a patient or ordering of an item or service.

Comment: Some commenters supported using alternative language to the direct connection standard, such as ''reasonably related and directly tied'' or ''directly connected or reasonably related.'' Many of these commenters asserted that alternative language would better convey the close nexus between this safe harbor and the coordination and management of care of a target patient population. Other commenters advocated for other changes to the standard, *e.g.,* replacing ''directly connected'' with only ''connected.''

Response: We are finalizing the standard, proposed at paragraph

1001.952(ee)(1), now codified at paragraph 1001.952(ee)(1)(ii) requiring that remuneration be used predominately to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. We are not finalizing the similar standard proposed at paragraph 1001.952(ee)(7) requiring that the value-based arrangement is directly connected to the coordination and management care of the target patient population, because doing so would introduce unnecessary duplication to the safe harbor. We believe the direct connection standard we are finalizing appropriately captures the relationship we are requiring (*i.e.,* a close nexus) between the value-based activities (for which protected remuneration must be used predominantly to engage in) and the coordination and management of care for the target patient population.

Comment: A commenter sought clarification as to whether remuneration tied to either receiving referrals or being included in a preferred provider network would be a value-based activity directly connected to the coordination and management of care.

Response: As stated elsewhere in this final rule, the making of a referral, standing alone, is not a value-based activity. Accordingly, neither the exchange nor use of remuneration tied solely to receiving patient referrals or being included in a preferred provider network would be a value-based activity, let alone one that is directly connected to the coordination and management of care. Were such conduct combined with other value-based activities, the ''direct connection'' standard could be met, depending on the facts and circumstances.

iii. No Furnishing of Medically Unnecessary Items or Services or Reduction in Medically Necessary Items or Services

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ee)(4)(iii) to require that the remuneration exchanged not induce VBE participants to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient.

Summary of Final Rule: We are finalizing, with modification, this condition at paragraph 1001.952(ee)(7)(iii). The modification provides that the *value-based arrangement* (rather than merely the remuneration) cannot induce the parties to furnish medically unnecessary items or services or reduce or limit medically necessary items or services.

Comment: Commenters universally supported this safeguard. A commenter separately encouraged OIG to develop clear guidelines to enforce this provision that do not unduly hinder the provision of health care or second-guess physicians' medical decision-making.

Response: We are finalizing this proposed protection for patient care and Federal program expenditures, with additional modifications to fully effectuate our intent. As stated in the OIG Proposed Rule, remuneration that induces a provider to order or furnish medically unnecessary care is inherently suspect. We likewise stated that a reduction in medically necessary services would be contrary to the goals of this rulemaking and could, in certain instances, be a violation of the CMP law provision relating to gainsharing arrangements.[38] We do not intend to protect arrangements that do either. Upon further consideration, we have determined that our choice of language for the regulatory text too narrowly focused on the remuneration in the care coordination arrangement and did not capture the full range of ways through which ill-intentioned parties might seek to use a value-based arrangement to induce medically unnecessary care or limit medically necessary care. Accordingly, to better reflect our intent, the final regulation text prohibits the value-based arrangement from inducing parties to order or furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient.

In response to the commenter's concern that this safeguard not unduly hinder physicians' medical judgment, this condition is not intended to interfere with medical decision-making; rather, it is intended to support decision-making in the best interests of patients without inappropriate financial influence. This requirement is a hallmark safeguard against fraudulent and abusive practices that could lead to inappropriate utilization, inappropriate steering of patients, or stinting on care. We note that a separate condition of the safe harbor prohibits potential limitations on VBE participant's ability to make decisions in the best interests of the target patient population.

iv. Remuneration From Individuals or Entities Outside the Applicable VBE

Summary of OIG Proposed Rule: We proposed at 1001.952(ee)(4)(iv) that the remuneration exchanged could not be funded by, or otherwise result from the contributions of, any individual or entity outside of the applicable VBE. We stated that we were considering a requirement that remuneration be provided directly from the offeror to the recipient.

Summary of Final Rule: We are not finalizing the proposed funding limitation or a requirement that remuneration be provided directly from the offeror to the recipient.

Comment: A few commenters supported the requirement prohibiting remuneration from individuals or entities outside the applicable VBE. Other commenters asked for exceptions to the requirement, such as exceptions for remuneration that would benefit the VBE's patients and where the donating third-party would have no direction or control over how the remuneration could be used. Other commenters opposed the requirement, stating that it would prevent VBE participants from deriving remuneration from a wide variety of appropriate outside funding sources, such as payors. Another commenter raised concerns that a VBE participant could lose safe harbor protection unfairly if it receives remuneration from another VBE participant that was funded by another party without recipient of the renumeration knowing that source of funding. We also received comments on OIG's consideration of whether to require that remuneration be provided directly from the offeror to the recipient, with such commenters stating that such a requirement would create unnecessary practical impediments.

Response: We are not finalizing the proposed requirement prohibiting parties to a value-based arrangement from exchanging any remuneration funded by, or otherwise resulting from the contributions of, an individual or entity outside of the applicable VBE. The purpose of these proposals was to ensure that protected arrangements would be closely related to the VBE, that VBE participants would be committed to the VBE and striving to achieve the coordination and management of care for the target patient population, and that non-VBE participants could not indirectly use the safe harbor to protect arrangements that are designed to influence the referrals or decision-making of VBE participants. On balance, we do not believe the proposed conditions would add appreciably to the program integrity protection offered by the combination of safeguards we are including in the final safe harbor, which address these same concerns. We seek to minimize practical impediments to use of the safe harbor by avoiding conditions we do not believe are needed. However, we emphasize that remuneration exchanged outside of

[38] Section 1128A(b) of the Act.

a value-based arrangement would not be protected by any of the value-based safe harbors.

We also are not finalizing the requirement considered in preamble to the OIG Proposed Rule that remuneration be provided directly from the offeror to the recipient. As explained in the OIG Proposed Rule, this requirement would have prohibited the involvement of individuals and entities other than the VBE or a VBE participant in the exchange of remuneration under a value-based arrangement, including, potentially third-party vendors and contractors. We agree with commenters asserting that this requirement could create unnecessary practical impediments that would be outweighed by any potential benefit of such a condition.

f. Taking Into Account the Volume or Value of, or Conditioning Remuneration on, Business or Patients Not Covered Under the Value-Based Arrangement

Summary of OIG Proposed Rule: We proposed in proposed paragraph 1001.952(ee)(5) to prohibit the offeror of the remuneration from taking into account the volume or value of, or conditioning an offer of remuneration on: (i) Referrals of patients that are not part of the value-based arrangement's target patient population; or (ii) business not covered under the value-based arrangement.

Summary of Final Rule: We are finalizing, without modification, the requirement in paragraph 1001.952(ee)(5).

Comment: While some commenters supported our proposal, asserting that the requirement appropriately differentiates between actual care coordination arrangements and improper pay-for-referral schemes, a few commenters did not support the requirement for various reasons. A commenter expressed concern that this requirement will be difficult to administer if recipients of remuneration have any business arrangements outside the VBE and posited that adequate remedies exist under current law to address the type of sham or abusive arrangements this provision intends to preclude from safe harbor protection, although the commenter did not identify any specific remedies. Another commenter asserted that this requirement should be removed to align physician incentives with the delivery of value-based care.

Conversely, a commenter opposed the proposed standard on the basis that it is too narrow and encouraged us to prohibit parties from taking into account the volume or value of referrals within the target patient population and to also prohibit exclusivity or minimum-purchase requirements in value-based arrangements. The commenter advocated for a modified condition that would restrict any remuneration that depends on or is calculated based on the volume or value of any Federal health care referrals, whether inside or outside the target patient population.

Response: We are finalizing this condition, as proposed. For purposes of the safe harbor, value-based care, including coordinated care, may take into account the volume of patients in the target patient population or value of referrals or other business generated between the parties resulting from referrals of the target patient population (*e.g.,* an offeror may base the number of hours it provides care coordination services to the recipient on the volume of patients in the target patient population). A complete prohibition on remuneration that takes into account the volume or value of referrals could operate as an actual or perceived barrier to safe harbor protection for the kinds of innovative care coordination arrangements that are the goal of this rulemaking. We are finalizing the limitation with respect to referrals of patients and business generated outside the target patient population under the value-based arrangement as an important safeguard to protect against remuneration offered under the guise of a value-based arrangement that is intended to induce the recipient's referrals of patients or business not covered under the value-based arrangement.

g. Contribution Requirement

Summary of OIG Proposed Rule: We proposed in paragraph 1001.952(ee)(6) to condition safe harbor protection on the recipient's payment of at least 15 percent of the offeror's cost for the in-kind remuneration (*i.e.,* a 15 percent contribution requirement). We also proposed at paragraph 1001.952(ee)(6) that the recipient make such a contribution in advance of receiving the in-kind remuneration, if a one-time cost, or at reasonable, regular intervals if an ongoing cost.

Summary of Final Rule: We are finalizing, with modification, the contribution requirement in paragraph 1001.952(ee)(6). Based on comments, we are revising the contribution requirement methodology to require recipients to pay at least 15 percent of either the offeror's cost of the remuneration, as determined using any reasonable accounting methodology, or the fair market value of the remuneration. We are finalizing, with only a minor technical modification to address syntax, our proposal that, if the remuneration is a one-time cost, the recipient must make the contribution in advance of receiving the in-kind remuneration; if the remuneration is an ongoing cost, the recipient must make any contributions at reasonable, regular intervals.

Comment: Many commenters expressed support for the proposed 15 percent contribution requirement or otherwise acknowledged that some level of contribution likely would be an appropriate safeguard to hold VBE participants accountable, promote engagement, and lower the risk that unnecessary or improper remuneration would be furnished pursuant to a value-based arrangement. The majority of commenters opposed any contribution requirement, with several asserting that such a requirement would be administratively burdensome; would necessitate onerous documentation and analysis, *e.g.,* documenting and tracking the exchange of remuneration, in addition to undertaking an analysis as to whether the items or services exchanged constitute remuneration in the first place; and would discourage parties from entering into beneficial value-based arrangements.

Response: We are retaining a 15 percent contribution requirement for purposes of the care coordination arrangements safe harbor. We proposed the contribution requirement to: (i) Increase the likelihood that the recipient would use the care coordination item(s) and service(s); (ii) ensure that the remuneration would be well-tailored to the recipient; and (iii) promote the recipient's vested interest in achieving the intended purpose of the value-based arrangement, namely, furthering the coordination and management of care of the target patient population.

We are not persuaded that the contribution requirement would be overly burdensome or chill participation in value-based arrangements. While there may be some administrative burden associated with a contribution requirement, on balance we believe this requirement is important to mitigate what OIG identified in the OIG Proposed Rule as traditional fraud and abuse risks, *e.g.,* inappropriately increased costs to the Federal health care programs or patients, corruption of practitioners' medical judgment, overutilization, and inappropriate patient steering.

Comment: Many commenters supported a lower contribution amount (or no contribution amount) for arrangements involving certain providers with financial constraints.

These commenters generally asserted that, absent an exemption from, or significant reduction in the amount of, the contribution requirement, many providers would not be able to afford to participate in value-based arrangements. Commenters had varying suggestions for who should qualify as a provider with financial constraints, including, for example, essential hospitals, critical access hospitals, Indian health care providers, not-for-profit social services organizations, free and charitable clinics, small and rural practices, and practices serving medically underserved areas. Some commenters offered potential definitions while others favored existing definitions, such as those promulgated by the U.S. Small Business Administration, CMS, and the Health Resources and Services Administration.

Response: Having considered the comments and the goals of this rulemaking, we are not reducing or eliminating the contribution amount for arrangements involving certain providers with financial constraints. While we remain sensitive to the limited resources of many types of potential VBE participants, including those cited by commenters, we believe that the contribution requirement serves as an important guardrail to prevent fraud and abuse under the guise of a value-based arrangement and an incentive for parties to develop arrangements that are both effective in coordinating and managing care and economically prudent. We believe the contribution requirement will help ensure that parties are serious about collaborating to achieve the purpose of coordinating and managing patient care and will deliberately design care coordination arrangements most likely to be effective at achieving quality and efficiency aims in an economically prudent manner. In addition, we decline to make exceptions to the 15 percent contribution requirement for categories of VBE participants (*e.g.,* small and rural practices) for several reasons. First, some designations can change over time (for example, a physician practice may qualify as a small practice at some points in time but not at others, depending on staffing changes), which could create confusion about the implementation of the contribution requirement when such a change occurs. Second, the same types of fraud and abuse risks associated with potentially valuable in-kind remuneration from a referral source apply equally to both larger or urban recipients, for example, and the types of recipients that requested an exemption from the 15 percent contribution requirement or a lower contribution percentage, such as small or rural providers. OIG's enforcement experience demonstrates that fraud is perpetrated by both small and large entities and happens across all geographic areas. Third, the 15 percent contribution requirement is based on the electronic health records items and services safe harbor at paragraph 1001.952(y)(11), which does not differentiate among recipients. Finally, in the context of the flexibilities of the overall safe harbor, the advantages from a compliance perspective of a single bright line standard outweigh the potential benefits of variable standards based on geographic location or other characteristics. Moreover, we have no basis for determining different amounts for different parties. Should the 15 percent contribution requirement pose a barrier to use of the safe harbor, parties are reminded that failure to fit in a safe harbor does not mean that an arrangement is necessarily unlawful and that OIG's advisory opinion process is also available.

Comment: At least one commenter suggested that the safe harbor except certain forms of in-kind remuneration (*e.g.,* remuneration that consists of cybersecurity technology and related services and IT-related updates, upgrades, and patches) from the contribution requirement.

Response: We decline to include any exceptions to the contribution requirement under the care coordination arrangements safe harbor because we believe that, in the context of this safe harbor, this requirement is important to mitigate traditional fraud and abuse risks and ensure that parties enter into arrangements that serve value-based purposes. However, we remind parties seeking safe harbor protection for the exchange of cybersecurity technology and related services that the cybersecurity technology and related services safe harbor, paragraph 1001.952(jj), is available to protect the exchange of cybersecurity items and services, provided all safe harbor requirements are met, and note that such safe harbor does not include a contribution requirement.

Comment: Commenters generally opposed the proposal that the contribution requirement be calculated based upon the offeror's cost. For example, a commenter asserted that an offeror's cost may be difficult to determine where the offeror has substantial development costs but small marginal costs for each individual recipient or user. Another commenter posited that this standard would provide insufficient flexibility because the benefit of the remuneration exchanged may be realized by one party more than the other, for example, where the remuneration exchanged between two or more parties primarily benefits the offeror versus the recipient. Commenters suggested various methodologies to calculate the contribution requirement, including: (i) The offeror's cost or fair market value; (ii) the offeror's cost or a price charged by the offeror to purchasers outside of the VBE; (iii) any reasonable accounting methodology; and (iv) an amount based on the price for that product or service (or a reasonably comparable product or service if it is new to the market) typically charged by the offeror to reasonably comparable customers outside VBEs. Another commenter recommended we define ''offeror's cost,'' whereas another commenter expressed concern that the standard would be difficult to implement because items or services that benefit patients could have little or no quantifiable independent value to the VBE recipient.

A commenter asserted that calculating cost may be difficult when tools and software are developed internally by the developer or manufacturer and made available by a VBE participant or acquired as part of a bundled sale under the discount safe harbor. A commenter also stated that there may be substantial development costs but only marginal costs for each individual recipient and that costs could be subject to proprietary and confidentiality obligations.

Response: In the OIG Proposed Rule, in addition to our proposal that the contribution requirement be calculated based upon the offeror's cost, we stated we were considering two other methodologies for determining the 15 percent requirement: Fair market value of the remuneration to the recipient or the reasonable value of the remuneration to the recipient. To afford parties additional flexibility, we are revising the contribution requirement methodology in this final rule to require recipients to pay at least 15 percent of either: (i) The offeror's cost of the remuneration, as determined using any reasonable accounting methodology; or (ii) the fair market value of the remuneration. As indicated in the OIG Proposed Rule, we are not requiring that parties obtain an independent fair market valuation. We selected fair market value rather than reasonable value because fair market value is a more specific standard, a widely used term in valuation, and common to many existing safe harbors such that many stakeholders and the government have experience with it. We are finalizing the

requirement as ''fair market value'' instead of ''fair market value of the remuneration to the recipient'' because we believe the inclusion of ''to the recipient'' could confuse generally accepted valuation methodologies due to its focus on only one party. We expect that parties to a value-based arrangement seeking protection under this safe harbor would use generally accepted valuation methodologies and principles in any determination of ''fair market value'' in relation to the contribution requirement, which could incorporate factors related to the recipient.

To provide parties flexibility we are not specifically defining ''offeror's cost'' or requiring a specific methodology for determining fair market value. To the extent costs are proprietary or confidential, depending on the circumstances, parties could meet this condition through the use of contractual provisions in their value-based arrangements to protect information from further disclosure or rely on the fair market value option to determine the 15 percent contribution requirement.

We are finalizing our proposal that, if the remuneration is deemed by the parties to be a one-time cost, *e.g.,* a one-time purchase of telehealth-related technology, the recipient must make the contribution in advance of receiving the in-kind remuneration; to the extent the remuneration is deemed by the parties to be an ongoing cost, *e.g.,* a subscription service to a data analytics tool, the recipient must make any contributions at reasonable, regular intervals, with the frequency of such payments documented in writing. We note that parties have the flexibility to structure the recipient's contribution payment as either a one-time or ongoing payment, depending upon the facts and circumstances of the arrangement and the parties' preference.

Comment: We received several comments advocating for or against the adoption of alternative proposals noted in the OIG Proposed Rule. For example, many commenters favored an across-the-board reduction in the contribution requirement from 15 percent to 5 percent. Other commenters backed an exemption to, or a significant reduction in, the contribution requirement for certain categories of remuneration, such as technology and technology-related items, although at least one commenter opposed this approach due to administrative burden concerns. Another commenter urged OIG to calibrate the contribution based on the financial need of the target patient population.

Response: We are retaining the 15 percent contribution requirement, as proposed, with the aforementioned methodology modifications. We believe that a contribution requirement lower than 15 percent would not achieve a sufficient level of accountability and engagement of the recipient. Moreover, we decline to vary the contribution requirement based upon the type of remuneration at issue or the arrangement's target patient population; such variation would introduce unnecessary operational complexity.

Comment: A commenter recommended that OIG take into account nonmonetary contributions from the recipient to the offeror for purposes of calculating the contribution requirement.

Response: To meet this safe harbor's contribution requirement, a recipient must pay at least 15 percent of the offeror's cost of the remuneration (as determined using any reasonable accounting methodology) or at least 15 percent of the fair market value of the remuneration. Parties to a care coordination arrangement where any nonmonetary contributions flow in both directions—from the offeror to the recipient and the recipient to the offeror—would need to assess any potential Federal anti-kickback statute implications for both streams of contributions. To the extent that both streams of contributions constitute remuneration, implicate the Federal anti-kickback statute, and the parties seek protection under the care coordination arrangements safe harbor, the parties must satisfy the contribution requirement for each stream of remuneration. There may be circumstances under which the parties could appropriately offset payments made to satisfy the contribution requirement for each stream, but any such assessment would be fact specific. For example, it would be appropriate for parties to offset payment amounts to satisfy the contribution requirement for separate streams of remuneration to reduce administrative burden, provided each stream of remuneration complied with the Federal anti-kickback statute. In contrast, it would be inappropriate for parties to offset payment amounts in an attempt to reduce a party's contribution requirement below 15 percent and any associated arrangement would not be protected by this safe harbor.

Comment: A commenter recommended that, for purposes of applying the 15 percent contribution requirement in the care coordination arrangements safe harbor, OIG recognize a VBE's good faith allocation of the in-kind remuneration across various arrangements. The commenter identified a number of manners in which it believed a reasonable allocation could be made (*e.g.,* patient needs associated with a particular arrangement, such as a chronic care program), and noted that in some cases, a reasonable allocation might be a per capita allocation of in-kind remuneration across all VBE participants.

Response: First, for the purposes of our response, we assume that the commenter means that the in-kind remuneration provided by the VBE or VBE participant to other VBE participants would be shared by various VBE participants to a value-based arrangement, or various value-based arrangements, under the same VBE (*e.g.,* a shared care coordinator or shared information technology system). To the extent that VBE participants to a value-based arrangement or various value-based arrangements are sharing in-kind remuneration provided by the VBE or another VBE participant, it would be reasonable—under both methodologies that parties can use to determine the contribution requirement—to reasonably and in good faith allocate the ''offeror's cost for the in-kind remuneration'' or the ''fair market value'' of the shared resources between the various VBE participants sharing in the resources.

As stated above, we would expect that parties to a value-based arrangement seeking protection under this safe harbor would use reasonable accounting methodologies and generally accepted valuation methodologies and principles in determining any appropriate allocation of the shared resources for the purposes of determining the ''offeror's cost for the in-kind remuneration'' or the ''fair market value'' in relation to the contribution requirement. We acknowledge that reasonable accounting methodologies and commonly accepted valuation principles would allow for consideration of the shared nature of the in-kind remuneration. We further highlight that we would not expect that any aggregate contribution amounts—from VBE participants sharing in any in-kind remuneration—result in a windfall to the offeror.

Comment: Some commenters expressed concern that a contribution requirement would upend the existing regulatory framework that parties rely on to assess whether an item or service constitutes remuneration. For example, a dialysis provider stated that a contribution requirement may unintentionally create a presumption that many care coordination activities

that do not constitute remuneration for purposes of the Federal anti-kickback statute are, in fact, remuneration with a specific value. The same commenter illustrated its concern by explaining that multiple Medicare conditions for coverage require dialysis facilities to coordinate dialysis patients' care with other providers, including physicians and nursing homes. The dialysis provider requested that OIG confirm that the following does not constitute remuneration: (i) The provider performs care coordination services because they are required to do so by Medicare or other payors' rules, other law, or to meet the clinical standard of care, and (ii) the care coordination services provided do not relieve another party of an obligation assigned to it by Medicare or other payors' rules or other law.

Response: The contribution requirement does not change the current regulatory framework for assessing whether an item or service exchanged between two or more parties constitutes remuneration under either the Federal anti-kickback statute or the Beneficiary Inducements CMP. As we have stated in prior OIG guidance on this issue, we view ''remuneration'' under the Federal anti-kickback statute to consist of anything of value in any form or manner whatsoever.[39] With respect to the request for guidance as to whether (i) care coordination services performed by a provider because they are required to do so by Medicare or other payors' rules, other law, or to meet the clinical standard of care, and (ii) care coordination services that do not relieve another party of an obligation assigned to it by Medicare or other payors' rules or other law, such services could constitute remuneration under the Federal anti-kickback statute. However, we remind readers that even if care coordination services constitute remuneration, the Federal anti-kickback statute is not necessarily implicated. For example, the Federal anti-kickback statute generally is not implicated for financial arrangements limited solely to patients who are not Federal health care program beneficiaries. Further, depending on the facts and circumstances (including the intent of the parties), the provision of care coordination services may implicate the Federal anti-kickback statute but not violate it.

Comment: Some commenters asserted that the proposed 15 percent contribution requirement is arbitrary or that there is no evidence a contribution requirement would mitigate fraud and abuse concerns. Other commenters suggested that the contribution requirement is duplicative of existing safeguards included in the care coordination arrangements safe harbor, *e.g.,* the requirement that remuneration must be used primarily to engage in value-based activities that are directly connected to the coordination and management of care of the target patient population.

Response: We disagree with the commenters. We believe the contribution requirement will promote accountability, fiscal responsibility, and greater engagement by the recipient. We note that contribution requirements have been implemented in other contexts, such as those included in the electronic health records items and services (EHR) safe harbor at paragraph 1001.952(y) and the Federal Communications Commission's Rural Health Care Pilot Program.[40] Moreover, we do not believe the contribution requirement is duplicative of other safeguards. While several conditions in the safe harbor promote accountability, the contribution requirement provides an objective, bright-line standard for parties that requires recipients in value-based arrangements to have a financial stake in the arrangement and encourages a tangible commitment to achieving the value-based arrangement's goals.

Comment: At least two commenters drew attention to the parallel contribution requirements in the care coordination arrangements and EHR safe harbors. For example, a commenter highlighted the perceived inconsistency of relying on the EHR safe harbor to justify our contribution requirement on the one hand and indicating that we were considering revisiting or eliminating the contribution requirement in the EHR safe harbor on the other. Another commenter sought to distinguish the care coordination arrangements safe harbor from the EHR safe harbor by stating that a contribution requirement may be appropriate in the EHR safe harbor because the EHR safe harbor has less stringent standards, but a contribution requirement is not warranted in the care coordination arrangements safe harbor. The commenter further asserted that the EHR safe harbor protects items and services that have clear independent value to the recipient, while items and services exchanged pursuant to value-based arrangements may not always have such independent value.

Response: In the OIG Proposed Rule, we considered removing the contribution requirement in the EHR safe harbor, but as discussed subsequently in this final rule, we are retaining the EHR safe harbor's contribution requirement. Accordingly, both the care coordination arrangements safe harbor and the EHR safe harbor, as finalized, include a 15 percent contribution requirement. We disagree that the EHR safe harbor has less stringent standards. The care coordination arrangements and EHR safe harbors have distinct requirements tailored to the type of remuneration that may be protected by the respective safe harbor. With respect to the commenter's suggestion that items and services exchanged pursuant to the care coordination arrangements safe harbor may not always have independent value to the recipient (in contrast to the EHR safe harbor), we note that any such determination would be fact specific. Moreover, the contribution requirement does not change any assessment of whether an item or service exchanged between two or more parties constitutes remuneration under the Federal anti-kickback statute. We remind stakeholders that to implicate the Federal anti-kickback statute, there must be ''remuneration'' offered, paid, solicited, or received in the transaction or arrangement at issue. If the Federal anti-kickback statute is not implicated by a transaction or arrangement, then safe harbor protection is not necessary. Consequently, we would expect arrangements that qualify under the care coordination arrangements safe harbor to involve remuneration exchanged between the parties.

h. Direct Connection to the Coordination and Management of Care

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ee)(7)(i) that a value-based arrangement must have a direct connection to the

[39] *See, e.g.,* OIG, Special Fraud Alert, 59 FR 65372, 65377 (Dec. 19, 1994), *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html;* OIG, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952, 35978 (July 29, 1991), *available at https://oig.hhs.gov/fraud/docs/safeharborregulations/freecomputers.htm. See also* OIG advisory opinions generally, *e.g.,* OIG Adv. Op. No. 20–02, where OIG states, ''For purposes of the anti-kickback statute, 'remuneration' includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.''

[40] *See, e.g.,* Federal Communication Commission, Rural Health Care Pilot Program FAQs, *available at https://www.fcc.gov/general/rural-health-care-pilot-program#faqs* (requiring eligible recipients to fund 15 percent of the cost of infrastructure design and construction of broadband networks for health care purposes, in recognition that a contribution requirement will ''incentiviz[e] participants to choose the most cost-effective services and equipment and refrain from purchasing a higher level of service or equipment than needed'') (as cited to by the Federal Communication Commission, *Promoting Telehealth for Low-Income Consumers,* 84 FR 36865, 36869 (July 30, 2019)).

coordination and management of care for the target patient population.

Summary of Final Rule: We are not finalizing the condition at proposed paragraph 1001.952(ee)(7)(i) because it would substantially duplicate the condition at paragraph 1001.952(ee)(1)(ii), which requires the remuneration to be used predominantly to engage in value-based activities that are directly connected to the coordination and management of care.

Comment: Commenters generally did not support the condition proposed at paragraph 1001.952(ee)(7)(i), albeit for varying reasons. Some took issue with the fact that the condition did not afford parties the flexibility to select any one of the value-based purposes available to VBEs, and rather tied parties to the value-based purpose relating to the coordination and management of care. Some commenters argued that this condition was not necessary in light of other safeguards included in the care coordination arrangements safe harbor.

Response: We are not finalizing the condition proposed at paragraph 1001.952(ee)(7)(i) because it would substantially duplicate the condition we are finalizing at paragraph 1001.952(ee)(1)(ii). With respect to the commenters that argued that the proposed condition did not afford parties the flexibility to select any one of the value-based purposes available to VBEs, and rather tied parties to the value-based purpose relating to the coordination and management of care, we refer commenters to the discussion of the condition we finalize at paragraph 1001.952(ee)(1)(ii), in section III.B.3.e.ii. of the preamble. There we explain, in part, that the care coordination arrangements safe harbor's conditions do not preclude a value-based arrangement from furthering other value-based purposes; however, the safe harbor does require that the remuneration exchanged be used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population.

i. Preserving Clinical Decision-Making

Summary of OIG Proposed Rule: In proposed paragraph 1001.952(ee)(7)(ii), we proposed that the value-based arrangement must not limit parties' ability to make decisions in the best interests of their patients.

We also proposed in proposed paragraph 1001.952(ee)(7)(iii) that value-based arrangements cannot direct or restrict referrals if: (i) A patient expresses a preference for a different practitioner, provider, or supplier; (ii) the patient's payor determines the provider, practitioner, or supplier; or (iii) such direction or restriction is contrary to applicable law or regulations under titles XVIII and XIX of the Act.

Summary of Final Rule: We are finalizing, with modification, the proposed condition that the value-based arrangement must not limit the VBE participant's ability to make decisions in the best interests of its patients and relocating it to paragraph 1001.952(ee)(7)(i). We are making a technical correction to change ''their patients'' to ''its patients.'' In paragraph 1001.952(ee)(7)(ii), we are finalizing the condition related to directing or restricting referrals with one clarification. We are deleting ''or regulations'' because ''regulations'' is already captured by the term ''applicable law'' in the final regulation. Thus, a value-based arrangement cannot direct or restrict referrals if such direction or restriction is contrary to applicable law under titles XVIII and XIX of the Act.

Comment: Commenters were very supportive of prohibiting any limitation on VBE participants' ability to make decisions in the best interests of their patients and limiting how the value-based arrangement can direct or restrict referrals to a particular provider, practitioner, or supplier. Many commenters asserted that these standards will protect patient choice and ensure the independence of medical or professional judgment.

Response: We agree with the commenters, and we are finalizing these two requirements—a prohibition on any limitation of VBE participants' ability to make decisions in the best interests of their patients, and limiting the circumstances in which parties to a value-based arrangement may direct or restrict referrals—to support patient choice and independent medical and professional judgment. Based on these conditions, remuneration exchanged as part of arrangements that unduly restrict patient choice or the independence of medical or professional judgment through inappropriate direction or restriction of referrals will not be protected. This requirement aims to ensure that VBEs and VBE participants that are parties to a value-based arrangement maintain their independent, medical, or other professional judgment without undue restriction. This condition is not intended to bar VBEs or VBE participants from communicating the benefits of receiving care from other VBE participants in the VBE.

Comment: Several commenters urged the OIG to adopt more robust safeguards to protect patient choice and ensure the independence of medical or professional judgment. A commenter recommended that health care professionals be given the ability to override any (i) practice guideline or standard; (ii) electronic health record technology; (iii) clinical-decision support software; (iv) computerized order entry program; or (v) policies that may be imposed or implemented by a VBE or payor if such an override is, in the professional judgment of the health care professional, consistent with their determination of medical necessity and appropriateness or nursing assessment, in the best interests of the individual patient, and consistent with the patient's wishes.

Another commenter asserted that the OIG Proposed Rule appears to give a provider the authority to direct a referral unless the patient otherwise expresses an alternative choice. The commenter recommended that we include a requirement that the VBE provide notice to patients informing them that: (i) The entity is participating in a financial risk-based program where the entity receives financial benefits under applicable conditions; (ii) referrals for care may be made to a restricted list of providers and practitioners; and (iii) the patient has the freedom to choose any qualified provider or practitioner and the right to reject any referral to a particular provider or practitioner if they have an alternative preferred provider or practitioner. Another commenter urged OIG to provide consumer-tested templates for VBEs to communicate with patients that they retain their rights to choose providers.

Response: With respect to the commenter's assertion that the OIG Proposed Rule appears to give the provider the authority to direct a referral unless the patient otherwise expresses an alternative choice, we note that the provision we are finalizing also prohibits the value-based arrangement from directing or restricting referrals where the patient's payor determines the provider, practitioner, or supplier, or where the direction or restriction is contrary to applicable law under titles XVIII and XIX of the Act. Moreover, nothing in this safe harbor gives providers authority to direct referrals. This provision describes one among several conditions of safe harbor protection, in this case a limitation on what a protected value-based arrangement can do.

With respect to the suggestion that providers be permitted to override various care protocols, guidelines, policies, or technology-driven systems, this safe harbor does not affect the authority of providers to do so. A

provider's obligation to comply with care protocols, guidelines, policies, or technology-driven systems is outside the scope of this final rule. This safe harbor speaks only to the conditions under which a value-based arrangement would receive prospective safe harbor protection under the Federal anti-kickback statute. The value-based arrangement may not limit the VBE participant's ability to make decisions in the best interests of its patients. Facts and circumstances demonstrating that the value-based arrangement has limited a VBE participant's ability to make decisions in the best interest of its patients would disqualify the remuneration exchanged pursuant to the value-based arrangement from protection under this safe harbor. In drafting the final rule on this point, we have been guided in part by experience with long-established rules in the physician self-referral law [41] and the Medicare Shared Savings Program [42] that address preservation of patient preferences and clinician judgment choice in the context of directed referrals.

While we appreciate the commenters' suggestions regarding patient notice, we did not propose a patient notice requirement in the OIG Proposed Rule for any of the three value-based safe harbors, and we are not including a patient notice requirement in this final rule. Such a requirement would add administrative burden without appreciably adding benefits, including protections against fraud and abuse, given the combination of conditions we are finalizing. Further, such notices, if executed poorly, could confuse patients. Parties may wish to provide notifications, and nothing in this rule prevents them from doing so. We are not providing templates for communications with patient regarding patient choice, and defer to providers, payors, and others to develop best practices for notices and other relevant communications.

Comment: A commenter urged the OIG to preclude safe harbor protection for any arrangement that involves paying for referrals and to protect against any given market player requiring referrals only to certain facilities. Another commenter recommended that VBEs be prohibited from taking any adverse action against a patient that chooses an alternative provider or practitioner.

Response: We share the commenter's concerns regarding abusive, pay-for-referral arrangements. We also recognize that legitimate care coordination arrangements may involve an exchange of remuneration between parties that are in a position to give or receive referrals and that referrals may be made between VBE participants coordinating and managing a patient's care through a value-based arrangement. One of the objectives of the care coordination arrangements safe harbor is to identify and define attributes of legitimate care coordination arrangements and afford protection only to remuneration exchanged under such arrangements. The requirements of this safe harbor and the value-based terminology (*e.g.,* value-based purpose, value-based activity, value-based arrangement) work together to achieve this objective. Abusive, pay-for-referral arrangements, such as an arrangement where an individual or entity is required to offer remuneration to a provider in order to receive that provider's referrals or an arrangement that encourages providers to steer patients in ways that are not in the patients' best interests, will not be able to meet the requirements of the safe harbor.

With respect to the commenter's concern regarding a particular person or entity requiring referrals only to certain entities, we believe these types of directed referral provisions may be problematic in certain instances but also are common features of many legitimate care coordination arrangements. As explained in the preceding response, the limitations we are adopting in this final rule reflect important safeguards to protect patient choice and independence of medical and professional judgment and effectuate an appropriate balance between the competing concerns of protecting legitimate care coordination arrangements and preventing inappropriate pay-for-referral schemes.

With respect to the recommendation that, as a condition of safe harbor protection, VBEs should be prohibited from taking any adverse action against a patient that chooses an alternative provider or practitioner, we note that nothing in the safe harbor limits or directs a patient's choice of provider or services, including a patient's choice to seek care outside the VBE. As indicated in the OIG Proposed Rule and implemented in this final rule, it is our intent that a patient can express a preference for a different practitioner, provider, or supplier and the value-based arrangement cannot restrict or limit that choice. Further, safe harbor protection does not extend to any arrangement where the value-based arrangement directs or restricts referrals to a particular provider, practitioner, or supplier if the patient's payor determines the provider, practitioner, or supplier or the direction or restriction is contrary to applicable law under titles XVIII and XIX of the Act.

j. Marketing of Items or Services or Patient Recruitment Activities

Summary of OIG Proposed Rule: We proposed in proposed paragraph 1001.952(ee)(7)(iv) that the value-based arrangement could not include marketing to patients of items or services or engaging in patient recruitment activities. We stated that we did not intend for this limitation to prohibit a VBE participant that is a party to a value-based arrangement from educating patients in the target patient population regarding permissible value-based activities.

Summary of Final Rule: We are finalizing, with modifications, this requirement at paragraph 1001.952(ee)(1)(iii). We have revised the language of the text at paragraph 1001.952(ee)(1)(iii) to clarify that the protected remuneration under the value-based arrangement may not be exchanged *or used* for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

Comment: Several commenters strongly supported our proposal, or, alternatively, advocated for the imposition of additional conditions to protect against abusive marketing practices. However, the majority of commenters on this topic either sought clarification on the parameters of the condition or opposed it altogether. A commenter asked OIG to define allowable educational activities and prohibited marketing activities, and another commenter questioned whether a distinction between marketing and educational activities is possible when, according to the commenter, the line between marketing and education is subjective and requires an intent-based inquiry. Another commenter suggested that OIG prohibit marketing and patient recruitment activities but permit efforts to make patients aware of the availability of items or services at times when the patient could reasonably benefit from such information. Other commenters requested that OIG provide guidance on, and specific examples of, the distinction between marketing and patient recruitment activities on the one hand, and patient education activities on the other. For example, a commenter asked whether a program to screen patients for fall risk and educate them on their risks and appropriate next steps would be considered patient education or a marketing activity. Another

[41] *See, e.g.,* 42 CFR 411.354(d)(4)(iv).

[42] *See, e.g.,* 42 CFR 425.305(b).

commenter asked whether a hospice's provision of free home-based palliative care services or room and board to patients unable to pay would constitute marketing or patient recruitment activities.

Numerous commenters opposed the prohibition on patient marketing and patient recruitment activities altogether, asserting that the condition is too broad. A commenter declared that marketing activities are necessary in order to meaningfully educate patients on their health care options, and another commenter claimed that a marketing and patient recruitment prohibition would limit a value-based enterprise's ability to leverage technology that might empower patients to make informed decisions and gain timely access to appropriate care. This commenter encouraged OIG to provide an exception for marketing-based technology that is used to achieve a defined health outcome under a value-based arrangement.

Response: We are finalizing a narrower condition than the condition proposed in the OIG Proposed Rule because we agree with the commenters that our proposed condition was broader than necessary to prevent the fraud and abuse concerns addressed by the condition. Rather than prohibiting all marketing and patient recruitment activities under a value-based arrangement, as proposed, the requirement we are finalizing prohibits the exchange of or use of remuneration for the purpose of marketing items or services provided by the VBE or VBE participants or for patient recruitment activities.

We use the terms ''marketing'' (*e.g.,* promoting or selling something), ''education'' (*e.g.,* informing, instructing, or teaching), and ''recruitment'' (*e.g.,* enlisting someone to do something) in accordance with their commonsense meanings. We are not defining in regulatory text ''marketing,'' ''patient recruitment activities,'' or ''education,'' or a similar term (note that the regulatory text does not use ''education'' or ''educational activities'' but we use such terms in our preamble explanation). We decline to define these terms: (i) In recognition that these terms are commonly understood; and (ii) to avoid overly prescriptive definitions that may chill appropriate educational activities. In lieu of regulatory definitions, we offer illustrative examples below to aid stakeholders in applying the safe harbor provision.

As noted in the OIG Proposed Rule, the proposed marketing and recruitment restriction would prevent misuse of the safe harbor by those seeking to use purported value-based arrangements to perpetuate fraud schemes through the purchase of beneficiaries' medical identity or other inducements to lure beneficiaries to obtain unnecessary care. As stated in the OIG Proposed Rule, our enforcement experience demonstrates that fraud schemes often involve a mixture of both inducements to lure beneficiaries to obtain unnecessary care and the use of marketing-like activities to steal patients' medical identities. In particular, OIG has long-standing concerns about marketing activities that involve personal contact with beneficiaries. For example, OIG has previously explained that door-to-door marketing, telephone solicitations, direct mailings, and in-person sales pitches or ''informational'' sessions can be extremely coercive, particularly when such activities target senior citizens, Medicaid beneficiaries, and other particularly vulnerable patients.[43]

Consequently, we believe that remuneration used for marketing and patient recruitment activities, regardless of whether the activities are driven by technology or tied to achieving a defined health outcome, remains suspect and requires fact-specific scrutiny under the Federal anti-kickback statute; therefore, we decline to provide safe harbor protection for such remuneration in this safe harbor.

Nevertheless, we acknowledge the benefits of objective educational materials to provide patients with general health care information and information about their health care options. We do not consider remuneration exchanged between parties to a value-based arrangement to (i) provide objective patient educational materials or (ii) engage in objective patient informational activities to constitute marketing or patient recruitment activities for purposes of this safe harbor condition. As we explained in the OIG Proposed Rule, this condition would not prohibit a VBE participant that is a party to the value-based arrangement from educating patients in the target patient population about permissible value-based activities.

A determination regarding whether remuneration is being exchanged or used for the purposes of marketing items or services or patient recruitment activities or for an educational activity requires a fact-specific analysis; however, the following examples illustrate how we distinguish between marketing and patient recruitment, on the one hand, and education on the other. Using examples from the OIG Proposed Rule,[44] if a SNF or home health agency placed a staff member at a hospital to assist patients in the discharge planning process, and in doing so, the staff member educated patients regarding care management processes used by the SNF or home health agency, this would not constitute marketing of items and services (provided the staff member only worked with patients that had already selected the SNF or home health agency and SNF or home-health agency care was medically appropriate for such patient). However, if the SNF or home health agency placed a staff member at a hospital to perform care coordination services and to market the SNF's or home health agency's services to hospital patients, the arrangement would not comply with this requirement because the remuneration being exchanged pursuant to the arrangement—the services offered by the staff member—would be exchanged for the purpose of engaging in marketing.

As an additional example, we would not consider actions, such as notifying a patient of the criteria used by a VBE participant to determine patient eligibility for care coordination services or informing the target patient population of potential health benefits that may be derived from care coordination for a patient's chronic condition, to be marketing or patient recruitment activities. This sort of targeted education to the patient is distinguishable from broader marketing and recruiting campaigns designed to sell products or services or recruit patients.

Notably, in some circumstances, it may not be necessary to make a distinction between marketing and education to determine whether an arrangement fits in a value-based safe harbor. If remuneration is exchanged pursuant to an arrangement that does not qualify as a ''value-based arrangement,'' as defined here, it is not eligible for safe harbor protection. For example, an arrangement solely for a direct-mail marketing campaign or other advertising would need to qualify as a value-based arrangement under the definition at paragraph 1001.952(ee) to be eligible to use a value-based safe harbor. We cannot envision a circumstance where such an arrangement would be a ''value-based arrangement'' as defined in this final rule or be eligible under this safe harbor. Should one VBE participant wish to

[43] OIG, OIG Adv. Op. No. 08–20 (Nov. 19, 2008), *available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-20.pdf.*

[44] 84 FR 55712 (Oct. 17, 2019).

engage in a direct-mail campaign that markets, in part, another VBE participant's services and the parties seek safe harbor protection for such arrangement, they should look to the personal services and management contracts safe harbor at paragraph 1001.952(d).

In response to the commenter's inquiry regarding a screening program for fall risk, it is not clear from the commenter's description whether the program would be part of a coordinated plan of care for a target patient population to improve outcomes or a marketing or patient recruitment activity to attract patients to the VBE or its participants. If the former, the arrangement could qualify for safe harbor protection, if all safe harbor conditions are met. If the latter, it would not be protected. Based on our oversight experience, we are concerned that a fall risk screening program could be misused as a marketing or patient recruitment activity if the screening program was not part of the coordination and management of care or an objective educational program. There is a risk that such a program could be used to lure beneficiaries to obtain unnecessary care. Whether a particular fall risk screening program is a marketing program, an educational program, or a value-based arrangement will depend on its specific facts and circumstances.

Additionally, we note that remuneration exchanged between parties to a value-based arrangement that is used to offer something of value to patients to incentivize them to obtain a fall screening examination from one of the parties would not be protected by this safe harbor. We have modified the regulatory text to make clear that prohibited marketing includes not only exchanging remuneration for the purpose of engaging in patient recruitment activities or marketing but also using remuneration for such purposes. This change effectuates our intent articulated in the preamble to the OIG Proposed Rule to limit the risk of the value-based arrangement being used as a marketing or recruiting tool to generate federally payable business for the VBE participant.[45] To illustrate how this condition would operate, the parties cannot exchange remuneration for the purpose of engaging in patient recruitment activities or marketing (*e.g.,* a SNF or home health agency placed a care coordinator at a hospital to market the SNF's or home health agency's services to hospital patients). In addition, the parties cannot use the remuneration for marketing or engaging in patient recruitment activities (*e.g.,* the hospital asks the care coordinator placed by the SNF or home health agency to send out mailings to the local community regarding the hospital's services).

Regarding the question about a hospice's provision of free home-based palliative care services or room and board to patients unable to pay, such an arrangement would not be protected by the care coordination arrangements safe harbor. This safe harbor is limited to remuneration exchanged between parties to a value-based arrangement, *i.e.,* between a VBE and VBE participant or between VBE participants. It does not encompass arrangements involving the exchange of remuneration to patients. Other safe harbors or exceptions to the Beneficiary Inducements CMP may be available to protect the provision of such items and services to patients, depending upon the facts and circumstances.

We reiterate that nothing in this safe harbor prevents VBEs or VBE participants from marketing their services. Indeed, arrangements need not have safe harbor protection to be lawful, and we observe that many legitimate health care entities lawfully market services without benefit of a safe harbor. However, value-based arrangements that include the exchange or use of remuneration for the purpose of marketing or patient recruitment would not be eligible for protection under the care coordination arrangements safe harbor.

Comment: A commenter requested that OIG address whether a VBE participant that is a payor and owns a company that provides remote monitoring devices or has a vendor relationship with a company that provides such devices could suggest certain device utilization for purposes of improved care.

Response: The commenter describes the recommendation or referral of a device by a VBE participant that is a payor and is affiliated with a company that provides remote monitoring devices but does not identify remuneration provided under the value-based arrangement. Without additional facts, we can only respond generally to the comment. First, we would highlight that this safe harbor does not protect free or reduced-priced items or services that sellers provide either as part of a product sale arrangement or ancillary to a value-based arrangement. Free or reduced-priced items and services provided either as part of a product sale arrangement or ancillary to a value-based arrangement may not need safe harbor protection or may be protected by other safe harbors.

Second, nothing in the safe harbor would prohibit a VBE participant from using remuneration it received pursuant to a value-based arrangement to inform the target patient population of the availability of care coordination activities it provides to patients (*e.g.,* patient monitoring) in a targeted, objective, and educational manner so long as the remuneration is not exchanged or used for marketing or patient recruitment activities. In this final rule, we have clarified that the content of the marketing the safe harbor prohibits is the marketing of items and services furnished by the VBE or a VBE participant to patients.

To the extent that payors or other VBE participants provide remuneration to patients in the form of a free device, such remuneration would not be protected by this safe harbor. We note that other safe harbors or exceptions to the Beneficiary Inducements CMP may be available to protect the provision of such items and services, depending upon the facts and circumstances.

Comment: A health system recommended that provider affiliation announcements be carved out of the definition of marketing or recruitment activities so that providers can inform patients that they participate in value-based arrangements. Another commenter similarly urged OIG to permit individuals or entities participating in a VBE to market themselves as VBE participants to patients.

Response: Remuneration exchanged between parties to a value-based arrangement may be used to inform patients in the target patient population that the VBE participant participates in the value-based arrangement without such information being considered a marketing or recruitment activity. However, whether broader advertising (that includes VBE participant-related information) would be considered a prohibited marketing or recruitment activity for safe harbor purposes would be a fact-specific determination. For example, as part of a larger value-based arrangement between a physician group and a hospital, a hospital provides tablets to the physician group, which the physician group uses for in-office patient asthma management education. If the education application used on the tablet identifies all VBE participants capable of helping the patients manage their asthma and provide other services, the tablet would not run afoul of the marketing prohibition because it is not being used to market or recruit patients. It informs patients of VBE participants

[45] 84 FR 77712 (Oct. 17, 2019).

capable of providing disease management and other services. However, if the hospital also used the tablets to send text messages, notifications, and other pop-ups that solicit the patient to receive services from VBE participants, the tablet would be marketing under this safe harbor because it is being used for broader advertising or patient recruitment activity. A tablet, as part of a care coordination arrangement, could be protected remuneration; however, if it is part of a larger marketing scheme, the tablet would not be protected because that scheme would not be eligible for protection under this safe harbor and would be subject to a separate analysis under the Federal anti-kickback statute. Similarly, if the tablet was used as part of larger data harvesting scheme for marketing purposes, that scheme would not be eligible for protection under this safe harbor and be subject to a separate analysis under the Federal anti-kickback statute.

Comment: A commenter sought clarification on how to interpret the marketing and patient recruitment prohibition in the context of Medicare Advantage beneficiaries, and, specifically, whether compliance with existing CMS and OIG requirements associated with marketing to, and recruitment of, Medicare Advantage patients would be sufficient to maintain protection under the value-based safe harbors. In a similar vein, a health insurer requested that OIG clarify its definition of marketing and patient recruitment activities, as it relates to pre-enrollment activities.

Response: While acknowledging that payors may be subject to a wide range of other regulations, including CMS regulations and guidance specific to Medicare Advantage plans, we do not believe that compliance with CMS marketing requirements is sufficient for purposes of the safe harbor. Medicare Advantage regulations relating to patient enrollment and marketing are specific to payor-patient interactions in that program. In contrast, the conditions of this safe harbor are focused on facilitating beneficial care coordination and addressing potential fraud and abuse risks related to the exchange of remuneration between and among providers and suppliers. We remind the commenter that compliance with the care coordination arrangements safe harbor, as with all Federal anti-kickback statute safe harbors, is voluntary, and Medicare Advantage plans, or their contractors, may continue to seek protection under other existing safe harbors.

Comment: Several commenters expressed concern that the prohibition on marketing and patient recruitment activities may conflict with existing CMS rules regarding discharge planning, or, at the very least: (i) Be inconsistent with the concept of a preferred provider network operating within the context of a VBE; or (ii) potentially limit VBE participants' ability to inform patients of the availability of items and services during the discharge planning process.

Response: The prohibition on the marketing of items and services and patient recruitment activities, as finalized, relates specifically to the remuneration exchanged. Thus, for example, if a skilled nursing facility provides remuneration to a hospital under a value-based arrangement in the form of a discharge planner, the discharge planner could not market or recruit patients to the skilled nursing facility; doing so would prevent the value-based arrangement from qualifying for safe harbor protection. Nothing in the safe harbor prevents the hospital from informing patients about available skilled nursing facilities during the discharge planning process.

This prohibition is not inconsistent with current CMS hospital conditions of participation regarding discharge planning, which require (among other conditions) that hospitals provide a comprehensive list of certain post-acute care providers, as applicable, to patients prior to discharge.[46] Providing a comprehensive list of post-acute care providers would not constitute exchanging or using remuneration for marketing or patient recruitment for safe harbor purposes. This would be true even if the discharge planner provided to the hospital in the prior example were the person furnishing the list to patients, provided the discharge planner did not market or recommend the skilled nursing facility or another VBE participant on the list.

This prohibition is not inconsistent with the potential for a preferred provider network to operate within the context of a VBE. Using the above discharge planner example, the remuneration could comply with the marketing and patient recruitment activity prohibition if, for example, the discharge planner only provides written educational materials regarding the preferred provider network to target patient population members and does not actively recruit patients to the skilled nursing facilities in the preferred provider network and does not market or recommend any particular provider on the list. It is incumbent on parties seeking to establish and operate preferred provider networks to do so in a manner that complies with all pertinent regulations, and our safe harbor requirements are not intended to interfere with or supplant other compliance obligations.

Comment: A commenter expressed concern that the proposed prohibition on marketing and patient recruitment would bar a VBE from publishing quality improvement or cost reduction data. The commenter declared that VBEs should be permitted to share performance data regarding VBE participants to help inform patient choice.

Response: We would not consider the publication of quality and cost data to constitute marketing or patient recruitment activity. Therefore, parties to a value-based arrangement could exchange remuneration for the purpose of publishing such data, and we believe such data may be beneficial to inform patient choice.

Comment: To mitigate OIG's concerns regarding marketing, a manufacturer suggested that OIG include as an additional safe harbor requirement that VBE participants disclose their participation in the VBE to patients, similar to the Medicare Shared Savings Program beneficiary notice requirements.

Response: We thank the commenter for its suggestion. As noted elsewhere in this rule, we did not propose a patient notice requirement in the OIG Proposed Rule and are not including a patient notice requirement for reasons explained elsewhere. However, VBE participants are not prohibited, as noted above, from utilizing notices to transparently disclose their participation in a VBE to patients.

k. Monitoring and Assessment

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ee)(8) that the VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person monitor and assess, no less frequently than annually, or once during the term of the value-based arrangement for arrangements with terms of less than 1 year: (i) The coordination and management of care for the target population in the value-based arrangement; (ii) any deficiencies in the delivery of quality care under the value-based arrangement; and (iii) progress toward achieving the evidence-based, valid outcome measure(s) in the value-based arrangement. We further proposed to require that the party conducting such monitoring and

[46] 42 CFR 483.42(c).

assessment report the results of the monitoring and assessment to the VBE's accountable body or responsible person (if the VBE's accountable body or responsible person is not itself conducting the monitoring and assessment).

Summary of Final Rule: We are finalizing the monitoring and assessment requirement, with modifications, at paragraph 1001.952(ee)(9). We are requiring that the VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person reasonably monitor and assess the following, no less frequently than annually, or once during the term of the value-based arrangement for arrangements with terms less than 1 year: (i) The coordination and management of care for the target patient population in the value-based arrangement; (ii) any deficiencies in the delivery of quality care under the value-based arrangement; and (iii) progress toward achieving the legitimate outcome or process measure(s) in the value-based arrangement. We are revising the proposed language—from specific evidence-based, valid outcome measure(s) to legitimate outcome or process measure(s)—to align with the standard for outcomes measures finalized in paragraph 1001.952(ee)(4), discussed at section III.B.3.b.

We also require that the party conducting such monitoring and assessment report their findings to the VBE's accountable body or responsible person (if the VBE's accountable body or responsible person is not itself conducting the monitoring and assessment). Finally, we are making a technical correction by adding ''the following'' and ''of the following'' to the introductory language of the paragraph for greater clarity about what must be monitored and assessed.

Comment: Many commenters supported an annual monitoring and assessment requirement, where monitoring is tailored to the complexity and sophistication of the VBE and VBE participants. A physician trade organization recommended that OIG require monitoring and assessment of a value-based arrangement's value-based activities instead of the coordination and management of care for the target patient population, and another commenter asserted that OIG should require monitoring and assessment of whether value-based activities meet any of the value-based purposes. A commenter urged that the monitoring and assessment provision require monitoring of utilization, referral patterns, and expenditure data to ensure that abuse is curtailed, and gaming is reduced. Another commenter supported heightened standards and conditions for monitoring and assessment but did not specify any such standards and conditions. Some commenters opposed a monitoring and assessment requirement, with a commenter stating that writing-related safeguards are sufficient to protect against fraud and abuse.

Response: We are finalizing a monitoring and assessment requirement because we believe it is a critical safeguard to ensure oversight of the value-based arrangement. We are not adopting the suggestion to expand the condition to require monitoring of all value-based activities instead of the coordination and management of the care for the target patient population. Paragraph 1001.952(ee)(1)(ii) of this safe harbor requires the remuneration exchanged to be used predominantly to engage in value-based activities related to the coordination and management of care for the target patient population; consequently, we believe that it is appropriate to require the monitoring and assessment to focus on this value-based purpose. Under this requirement, the responsible party must monitor and assess whether and how the coordination and management of care is being implemented. ''Coordination and management of care'' is defined at paragraph 1001.952(ee)(14) for purposes of this safe harbor as the deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population. Thus, we expect any monitoring and assessment to evaluate how the value-based arrangement is or is not achieving this value-based purpose, as defined in this final rule. The monitoring and assessment may identify opportunities to reevaluate the value-based activities the parties are undertaking and the manner in which they are undertaking them to improve their chances of achieving this value-based purpose.

While we are not requiring monitoring and assessment of utilization, referral patterns, and expenditure data, monitoring and assessment of such data may be a best compliance practice for many arrangements, depending on the complexity and sophistication of the VBE participants, the VBE, and the value-based arrangement and available resources. We have added ''reasonably,'' to the monitoring and assessment provision to codify that, for all value-based arrangements, monitoring and assessment should be reasonable in relation to the complexity and sophistication of the VBE participants, the VBE, and the value-based arrangement and available resources.[47] We would expect parties to do as much as is appropriate based on the complexity and sophistication of the VBE participants, the VBE, and the value-based arrangement and available resources, but nothing in this provision should be construed to stop parties from having more robust monitoring and assessment processes than those described herein. This requirement both: (i) Provides flexibility for VBE participants associated with smaller, less-sophisticated VBEs and value-based arrangements to effectuate relatively more modest monitoring and assessment processes; and (ii) requires VBE participants associated with more complex and sophisticated VBEs and value-based arrangements to develop and operate appropriately complex and robust monitoring and assessment processes.

Comment: A commenter expressed concern that the annual monitoring and assessment requirement may have limited impact unless: Patients have a clearly articulated pathway for communicating and resolving concerns; outcome measures are valid and reflect outcomes important to patients; and results are reported to the Department or another oversight entity. Another commenter asked OIG to provide more information on the monitoring and assessment requirement and, specifically, to outline the reporting, auditing, and general oversight requirement of each VBE participant in the VBE.

Response: We appreciate the commenter's concern regarding the potential limited impact of the monitoring and assessment requirement. We are not requiring parties to value-based arrangements to establish specific protocols for receiving and addressing patient concerns or to report data to the Department, except as otherwise set forth in paragraph 1001.952(ee)(12), which requires that the VBE or VBE participant make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this safe harbor. However, we are finalizing the requirement for parties to establish one or more legitimate outcome or process measures, and to monitor and assess certain information.

[47] 84 FR 55713 (Oct. 17, 2019).

Specifically, to comply with the monitoring and assessment requirement, either the VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person must reasonably monitor and assess: (i) The coordination and management of care for the target patient population in the value-based arrangement; (ii) any deficiencies in the delivery of quality care under the value-based arrangement; and (iii) progress toward achieving the legitimate outcome or process measure(s) in the value-based arrangement. While, as stated above, the final safe harbor does not require the establishment of specific monitoring and assessment protocols or prescribe how VBEs must receive and address any patient concerns, we note that, as part of any VBE's regular monitoring activities, it would be a good compliance practice to establish a mechanism through which patients and others could submit reports related to, for example, deficiencies in the delivery of quality care under the value-based arrangement. Further, it would be a good compliance practice, as part of any VBE's regular monitoring and assessment activities, to assess any credible reports of, for example, deficiencies in the delivery of quality care under the value-based arrangement to determine their validity and any potential triggering of the termination and corrective action provision.

Again, the final rule does not prescribe a one-size-fits-all approach for monitoring and assessment, nor does it specify the reporting, auditing, and general oversight requirement of each VBE participant in the VBE. This lack of specificity is designed to allow VBEs (and their VBE participants) flexibility to establish a monitoring and assessment program that is reasonable for that particular VBE and value-based arrangement. As stated above, the monitoring and assessment processes for each value-based arrangement should be reasonable in relation to the complexity and sophistication of the VBE, VBE participants, and value-based arrangement. Given the flexibility parties have to form VBEs and value-based arrangements of varying levels of complexity, we anticipate that the monitoring and assessment processes for the diverse value-based arrangements that could be protected by this safe harbor may vary.

Comment: A commenter expressed concern that, if the party responsible for monitoring and assessment does not comply with the requirements of the safe harbor, that party's noncompliance places other parties at risk through no fault of their own.

Response: A safe harbor applies only where each condition of the safe harbor is squarely met. Therefore, if the party responsible for monitoring and assessment does not perform its responsibility in accordance with the safe harbor requirements, the remuneration exchanged pursuant to the value-based arrangement would not receive protection. However, where another party has done everything that it reasonably could to comply with the safe harbor requirements applicable to that party but the remuneration exchanged loses safe harbor protection as a result of another party's noncompliance, the party's efforts to take all possible reasonable steps would be relevant in a determination of whether such party had the requisite intent to violate the Federal anti-kickback statute.

Comment: Commenters expressed concern regarding, and urged flexibility for, the requirement for monitoring and assessment of progress toward evidence-based outcome measures. For example, a commenter asserted that participants to a new value-based arrangement need time to achieve success, as evidenced by the performance results of Medicare Shared Saving Program, and may not be able to progress quickly towards the outcome measures. Commenters noted that factors beyond a provider's control can impact outcomes and that interventions such as primary care, preventive services, and chronic care management may yield benefits that take numerous years to materialize.

Response: For a number of reasons, we believe the responsible party or parties should monitor and assess progress toward the outcome or process measure(s) the parties establish. Such monitoring and assessment may reveal whether efforts to achieve the outcome measure(s) have led to improvements or deficiencies in patient care; whether the outcome measure(s) the parties initially established continue to be the best goalposts for achieving one or more value-based purposes; and whether the items or services the offeror provided under the value-based arrangement, such as care coordination services, are effective tools for driving beneficial changes in care delivery. We agree with commenters that factors beyond a VBE participant's control could impact outcomes and that benefits of outcome measures could manifest over a longer timeframe; for this reason, the requirement for monitoring and assessment does not mandate that the parties achieve the outcome or process measure(s) on any particular timeframe.

l. Termination of the Arrangement

Summary of OIG Proposed Rule: We proposed at proposed paragraph 1001.952(ee)(9) that the parties terminate the value-based arrangement within 60 days if the VBE's accountable body or responsible person determines that the value-based arrangement: (i) Is unlikely to further the coordination and management of care for the target patient population; (ii) has resulted in material deficiencies in quality of care; or (iii) is unlikely to achieve the evidence-based, valid outcome measure(s). We said we were considering for the final rule, and sought comments on, an alternative to the proposed termination requirement that would instead allow for remediation—within a reasonable timeframe—before any required termination.

Summary of Final Rule: We are finalizing, with modifications, a termination provision for this safe harbor at paragraph 1001.952(ee)(10). Under the final rule, if the VBE's accountable body or responsible person determines, based on the monitoring and assessment conducted pursuant to paragraph 1001.952(ee)(9), that the value-based arrangement has resulted in material deficiencies in quality of care or is unlikely to further the coordination and management of care of the target patient population, the parties must, within 60 days, either terminate the arrangement or develop and implement a corrective action plan designed to remedy the deficiencies within 120 days and, if the corrective action plan fails to remedy the deficiencies within 120 days, terminate the value-based arrangement.

Comment: Some commenters expressed support for our proposed termination requirement, but many expressed concerns about what it would mean in practice. Many commenters supported the alternative we described in the preamble to the proposed rule that would allow for remediation, within a reasonable timeframe, before any required termination. These commenters noted a variety of operational and policy concerns with mandating termination within 60 days. For example, some commenters noted that complex arrangements may require more than 60 days to unwind responsibly. Some commenters suggested that a cure period be permitted where the VBE determines that a plan of correction may be devised to cure the deficiencies, and others suggested that remediation should be an option, but not a requirement. With respect to the length of a remediation

period during which parties could develop and implement a corrective action plan, commenters suggested a variety of time periods, ranging from 90 days to 1 year. Multiple commenters suggested a 120-day period. Another commenter suggested that any termination requirement should be suspended indefinitely as long as the parties are working in good faith to implement a corrective action plan. A commenter also noted that there is a difference between arrangements that are not making progress and those that are causing harm and suggested that the latter require immediate termination. Finally, a commenter requested that OIG clarify that parties do not have an obligation to assess for any events that trigger the termination provision on an ongoing basis, but instead are required to do so annually or prior to renewal of an agreement.

Response: We appreciate commenters' concerns regarding the potential challenges associated with requiring termination within 60 days if the VBE's accountable body or responsible person determines one or more of the triggering events has occurred. Several changes in the final rule address many of the concerns expressed by the commenters. The final rule provides more flexibility by requiring the parties, within 60 days, either to terminate the arrangement or to develop and implement a corrective action plan in the event the VBE's accountable body or responsible person determines that the value-based arrangement has resulted in material deficiencies in quality of care or is unlikely to further the coordination and management of care for the target patient population. The option for corrective action plans is consistent with our statements in the OIG Proposed Rule that we were considering allowing for remediation within a reasonable timeframe and that our goal is a reasonable but also prompt termination of arrangements that are no longer serving the goals for which safe harbor protection is offered.

The final rule does not require the parties to terminate the arrangement or implement a corrective action plan if the VBE's accountable body or responsible person determines that the value-based arrangement is unlikely to achieve its legitimate outcome or process measures. This safe harbor does not require the recipient to achieve an outcome or process measure. Also, the safe harbor permits the parties to the value-based arrangement to modify outcome or process measures prospectively, as long as other elements of the safe harbor continue to be met (for example, a change to an outcome measure would be a material change to the value-based arrangement that would need to be documented in writing and signed by the parties, in accordance with paragraph 1001.952(ee)(3)).

With respect to the option to develop and implement a corrective action plan, the final rule requires that such plan be designed to remedy the identified deficiencies within 120 days. If the corrective action plan fails to remedy the deficiencies within 120 days, the parties are required to terminate the value-based arrangement, and safe harbor protection for remuneration exchanged pursuant to the value-based arrangement would no longer be available. We selected a 120-day period based on recommendations from commenters and because we believe this time period is both long enough to allow a meaningful opportunity to remediate the deficiencies and short enough to necessitate diligent attention by the parties.

With respect to the commenter who asserted that a determination that the value-based arrangement has resulted in patient harm should require immediate termination, we appreciate the commenter's concern, and we agree that such a determination is a serious finding that should prompt immediate attention by the parties. We did not include a ''patient harm'' provision in the OIG Proposed Rule because incidents of patient harm will always be ''material deficiencies in quality of care,'' that would trigger this condition. However, not all material deficiencies in quality of care necessarily mean that there has been patient harm.

Finally, with respect to the commenter that requested clarification regarding the frequency with which parties must assess for any events that would trigger the termination or corrective action provision, we note that, consistent with the OIG Proposed Rule, this final rule ties the termination of the value-based arrangement or implementation of a corrective action to certain triggering events identified through ''monitoring and assessment.'' Monitoring and assessment must occur no less frequently than annually or at least once during the term of the value-based arrangement for arrangements with terms of less than 1 year. Thus, at a minimum, the party or parties responsible for monitoring and assessment must monitor the matters listed in the regulation at paragraph 1001.952(ee)(9) and report the results so that the accountable body or person can make a determination as to whether any of the events that trigger the termination or corrective action provision have occurred. We note that it would be a best compliance practice to ensure monitoring and assessment also involves receiving and assessing reports and other information related to the circumstances that must be monitored and assessed (*e.g.,* deficiencies in the delivery of quality care under the value-based arrangement). These reports would inform the accountable body or responsible person's determination regarding termination or corrective action under paragraph 1001.952(ee)(10).

Comment: A commenter expressed concern that the safe harbor contains too much deference to the subjective beliefs and determinations of the VBE participants, who the commenter asserts are self-interested. The commenter recommended that the termination provision in the safe harbor be revised to require termination if the information available to the VBE's accountable body or responsible person indicates that a triggering event has occurred. The commenter also recommended that the safe harbor specify that the VBE bears the burden of proof with respect to the question of whether the information available to the VBE's accountable body or responsible person required termination of the value-based arrangement.

Response: We believe that the revisions we are adopting in this final rule, which require termination or a corrective action plan if the VBE's accountable body or responsible person reaches one of two determinations help to mitigate the commenter's concerns regarding excessive deference to the subjective beliefs of the VBE participants. We do not believe it is necessary to specify that the VBE bears the burden of proof with respect to whether termination was required because any party seeking to avail themselves of the protection of a safe harbor generally bears the burden of proof that they meet the requirements of the safe harbor.

Comment: Several commenters raised concerns regarding our proposal to require termination if the VBE's accountable body or responsible person determines that the value-based arrangement is unlikely to achieve the evidence-based, valid outcome measure(s). For example, several commenters noted that it may take time to see results and that results may plateau at certain times. Commenters suggested that this provision may result in parties' prematurely judging an arrangement's success or failure and that 60 days was an arbitrary timeframe. Another commenter expressed concern that the termination provision implies that an arrangement could move in and

out of compliance with the safe harbor as performance changes from month to month. Another commenter requested that participants be permitted to modify measures prospectively, rather than have to terminate the value-based arrangement.

Response: We appreciate the concerns raised by commenters, and we are not finalizing the proposed requirement that the parties terminate the arrangement if the VBE's accountable body or responsible person determines that the value-based arrangement is unlikely to achieve the outcome measure(s). We believe that requiring termination, or a corrective action plan, upon such a determination is at odds with other elements of this safe harbor. As we have stated elsewhere, this safe harbor does not require that the value-based arrangement result in a particular level of performance on the outcome or process measure. It requires that the parties identify an outcome or process measure and that the outcome or process measure relates to the remuneration exchanged under the arrangement. We also wish to clarify that the safe harbor permits the parties to modify the outcome or process measure prospectively during the term of the agreement, as long as the other elements of the safe harbor continue to be met and the modification is memorialized in a writing signed by the parties.

We caution, however, that this safe harbor separately requires the VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person to reasonably monitor, assess, and report progress toward achieving the outcome or process measure. There may be circumstances where such monitoring and assessment of outcome or process measure progress may generate a finding that indicates that the value-based arrangement no longer meets all of the requirements of the safe harbor. For example, the finding may indicate that the remuneration exchanged is not being used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. Thus, while we are not creating an affirmative obligation to terminate or enter into a corrective action plan based on a determination that the value-based arrangement is unlikely to achieve the selected outcome or process measure, we caution that parties to a value-based arrangement who wish to be protected under the safe harbor should periodically evaluate compliance with safe harbor standards.

m. Diversion, Resell, or Use for Unlawful Purposes

Summary of OIG Proposed Rule: In proposed paragraph 1001.952(ee)(10), we proposed that an exchange of remuneration would not be protected under the care coordination arrangements safe harbor if the offeror knows or should know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose.

Summary of Final Rule: We are finalizing, without modification, this requirement at paragraph 1001.952(ee)(11).

Comment: We received very few comments on this proposal. Some commenters expressed support for the provision, while another commenter raised concerns that this standard would be difficult for individual providers and small group practices to understand and comply with because the standard is not specifically defined.

Response: We believe that the standard is straightforward. Where an offeror knows, or should know, that the recipient is likely to divert or resell the remuneration, or otherwise use it for an unlawful purpose, the remuneration is not protected by the safe harbor. This could arise in cases where the recipient's intended diversion is overt. For example, where a recipient expressly states its intent to sell the items received from the offeror to third parties, it would make clear its intended diversion. It can also arise, for example, where the nature or scope of the remuneration offered to the recipient is such that the offeror should know that diversion or resale is likely, such as where a VBE participant provides remuneration far in excess of what could reasonably be needed for the recipient to undertake the value-based activity for which the remuneration is intended and the remuneration is transferable in nature. For example, if a VBE participant provides handheld tablets to another VBE participant to facilitate coordination and management of care, but the offeror provides substantially more tablets than could reasonably be used by the recipient for the intended purpose (*e.g.,* 100 tablets when ten are objectively sufficient for the intended use), then the offeror might reasonably know that the recipient is likely to divert or resell the excess tablets. In sum, this standard is an explicit statement of what is otherwise implicit in the conditions of the care coordination arrangements safe harbor: The exchange of remuneration that the offeror knows or should know is likely to be diverted, resold, or used by the recipient for purposes other than the coordination and management of care of a target patient population would not be protected under this safe harbor.

n. Materials and Records

Summary of OIG Proposed Rule: To enhance transparency, we proposed a requirement at proposed paragraph 1001.952(ee)(11) that VBE participants or the VBE make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this safe harbor. We solicited comments regarding whether we should require parties to maintain materials and records for a set period of time (*e.g.,* at least 6 years or 10 years).

Summary of Final Rule: We are finalizing, with modifications, the materials and records requirement at paragraph 1001.952(ee)(12). The final rule specifies that, for a period of at least 6 years, the VBE or its VBE participants must maintain records and materials sufficient to establish compliance with the conditions of the safe harbor.

Comment: While we received relatively few comments on this condition, commenters were generally supportive of our proposal. In response to our solicitation regarding whether we should require parties to maintain materials and records for a set period of time, *e.g.,* 6 years or 10 years, multiple commenters were in favor of a 6-year retention period, with one stating that this approach would facilitate alignment with CMS's proposed rule and existing HIPAA requirements.

Response: We are persuaded that a 6-year retention period will promote transparency while aligning with the corresponding requirement in CMS's final rule. We have modified the relevant provisions in the care coordination arrangements, substantial downside financial risk, and full financial safe harbors.

Comment: A commenter questioned the need for a materials and records requirement because maintenance of these materials is already part of any compliance program. The same commenter further questioned whether OIG would bring an investigation or pursue a Federal anti-kickback statute case based solely on the failure to satisfy a documentation requirement rather than the underlying substantive safeguards.

Response: We continue to believe this requirement promotes transparency and gives parties notice that the Secretary may request materials and records

sufficient to demonstrate compliance with the care coordination arrangements safe harbor. We further note that not all parties seeking protection under this safe harbor may have a compliance program or may have developed one that requires maintenance of materials and records for less than 6 years.

Safe harbors offer voluntary protection from liability under the Federal anti-kickback statute for specified arrangements, and no entity or individual is required to fit within a safe harbor. Failure to fit within a safe harbor does not mean a party has violated—or even implicated—the Federal anti-kickback statute, it simply means the party may not look to the safe harbor for protection for that arrangement. For a party to assert safe harbor protection, all of the safe harbor's conditions must be satisfied, including any condition related to materials and records. Further, it would be prudent for any party relying on a safe harbor to protect certain remuneration to document in some form compliance with that safe harbor. Decisions regarding enforcement actions are made based on application of the Federal anti-kickback statute to the specific facts and circumstances presented by an arrangement.

Comment: A commenter stated that OIG should adopt additional requirements related to materials and records, including contemporaneous documentation of, among other things, the VBE's belief that the value-based arrangement is reasonably designed to achieve a value-based purpose, the specific basis for such belief, and the VBE's reasonable anticipation that particular evidence-based, valid outcome measures will advance the coordination and management of care of the target patient population.

Response: We decline to require the specific requested certifications. We intentionally drafted the materials and record requirement broadly to avoid creating a list of all documentation that parties must develop and maintain to comply with this condition of the safe harbor. Moreover, we do not seek to increase administrative burden by prescribing the manner in which parties must document their compliance.

Comment: A health system stated that the proposed care coordination arrangements safe harbor included burdensome reporting requirements and expressed concern about the large volume of paperwork that would go back and forth between ACOs and HHS or CMS.

Response: We disagree with the commenters' assertion that the materials and records requirement is burdensome. To the extent parties wish to avail themselves of the protection of this safe harbor, we believe it is reasonable to require them to maintain documentation that demonstrates their compliance with its terms. With respect to the commenter's concern about the exchange of large volumes of paperwork, we note that parties must only furnish such documentation to the Secretary upon request. We do not anticipate this requirement will necessitate frequent exchange of paperwork between, for example, an ACO and OIG.

Comment: A medical device manufacturer expressed concern that materials and records submitted to the Secretary pursuant to this condition would be subject to the Freedom of Information Act or other disclosure requirements. The manufacturer stated such materials could include proprietary and confidential trade secret information.

Response: OIG is subject to the Freedom of Information Act (FOIA) and the Department's FOIA regulations set forth at 45 CFR part 5. These regulations provide that submitters of records may designate in writing that all or part of the information contained in such records is exempt from disclosure under FOIA exemption 4—covering trade secrets and confidential commercial or financial information—at the time they submit such records or within a reasonable time thereafter. The Department, including OIG, will make reasonable efforts to notify submitters of records if the Department determines that material that submitters have designated as exempt from disclosure under FOIA exemption 4 may have to be disclosed in response to a FOIA request. Under the Department's FOIA regulations, submitters have an opportunity to respond and, if desired, file a court action to prevent disclosure of exempt records.

o. Additional Proposed Safeguards

i. Bona Fide Determination

Summary of OIG Proposed Rule: We considered a condition that would require that, in advance of, or contemporaneous with, the commencement of the applicable value-based arrangement, the VBE's accountable body or responsible person make two *bona fide* determinations with respect to the value-based arrangement: (i) The value-based arrangement is directly connected to the coordination and management of care for the target patient population; and (ii) the value-based arrangement is commercially reasonable, considering both the arrangement and all value-based arrangements within the VBE.[48]

Summary of Final Rule: We are not finalizing the proposed condition.

Comment: We received relatively few comments on this proposal. Commenters either expressed general statements of support or opposition, with a commenter who opposed the condition asserting that such *bona fide* determinations would add unnecessary complexity to demonstrating compliance with the safe harbor.

Response: We are not finalizing this requirement. We believe the goal of this proposed safeguard—ensuring appropriate oversight by the VBE's accountable body or responsible person—is achieved through the combination of other conditions included in this safe harbor. We do not believe this condition is needed to prevent fraud or abuse in light of the totality of other conditions we are finalizing in this rule.

ii. Prohibition on Cost-Shifting

Summary of OIG Proposed Rule: We considered, and sought comment on, a condition prohibiting VBEs or VBE participants from billing Federal health care programs, other payors, or individuals for the remuneration exchanged under the value-based arrangement; claiming the value of the remuneration exchanged under the value-based arrangement as a bad debt for payment purposes under a Federal health care program; or otherwise shifting costs to a Federal health care program, other payors, or individuals.

Summary of Final Rule: We are not finalizing the proposed condition.

Comment: We received comments expressing either general support for or opposition to this proposed safeguard. For example, in support of finalizing a cost-shifting prohibition, a commenter stated that a value-based enterprise's decision to offer remuneration in the context of a value-based arrangement should not make other parties financially responsible for such payments. A commenter argued that this proposed safeguard, among others, would be duplicative of other requirements in the safe harbor or be incompatible with or irrelevant in a value-based system. The commenter asserted that the additional safeguards proposed by OIG, including a prohibition on cost-sharing, would create an additional barrier to value-based arrangements rather than breaking down barriers that already exist. Other commenters, including Tribal organizations, advocated against the

[48] 84 FR 55714 (Oct. 17, 2019).

inclusion of a cost-shifting prohibition, stating such a safeguard is unnecessary because improvements in care coordination result in overall savings to the Federal Government even if they result in additional referrals or payments by Medicare and Medicaid.

Response: Having considered the comments, we are not finalizing a cost-shifting prohibition. On balance, we conclude that the combination of conditions in the final safe harbor will adequately protect against fraud and abuse risks, and an additional safeguard related to cost-shifting is not necessary in the context of the value-based safe harbors. We did not intend to limit appropriate billing of Federal health care programs or other payors for medically necessary items and services furnished in connection with value-based care. As we explained in the OIG Proposed Rule, we do not want to exclude arrangements from safe harbor protection that involve legitimate shifting of costs that result from achieving care coordination goals or other value-based purposes. As we explained, depending on the arrangement, one might expect to see increases in primary care costs or costs for care furnished in home and community settings paired with reductions in unnecessary hospitalizations, duplicative testing, and emergency room visits; one also might see increases in remote monitoring or care management services. Parties remain responsible for billing Federal health care programs and other payors in accordance with their program rules.

iii. Fair Market Value Requirement and Restriction on Remuneration Tied to the Volume or Value of Referrals

Summary of OIG Proposed Rule: We stated that we were considering including one or both of the following conditions in the care coordination arrangements safe harbor: (i) A fair market value requirement on any remuneration exchanged pursuant to a value-based arrangement; and (ii) a prohibition on VBE participants determining the amount or nature of the remuneration they offer, or the VBE participants to whom they offer such remuneration, in a manner that takes into account the volume or value of referrals or other business generated, including both business or patients that are part of the value-based arrangement and those that are not.

Summary of Final Rule: We are not finalizing either proposed condition in the care coordination arrangements safe harbor.

Comment: While we received some comments expressing support for these conditions, the overwhelming majority of commenters opposed the inclusion of a fair market value requirement or of a prohibition on determining the amount or nature of the remuneration in a manner that takes into account the volume or value of referrals or other business generated. While varying in their rationales, commenters generally asserted that including either safeguard would constrain care coordination efforts. Several commenters supported the condition that would prohibit taking into account the volume or value of referrals but recommended limiting this condition to patients who are not part of the value-based arrangement.

Response: In this final rule, we are not adopting a blanket prohibition on determining the amount or nature of remuneration in a manner that takes into account the volume or value of referrals or other business generated; rather, we are finalizing a narrower prohibition that the offeror of the remuneration cannot take into account the volume or value of, or condition an offer of remuneration on: (i) Referrals of patients that are not part of the value-based arrangement's target patient population; or (ii) business not covered under the value-based arrangement. We stated in the OIG Proposed Rule, and we continue to believe, that fair market value requirements and restrictions that prohibit paying remuneration based on the volume or value of referrals help ensure that protected payments are for legitimate purposes and are not kickbacks. For this reason, we included a safeguard in paragraph 1001.952(ee)(5) that requires, as a condition of safe harbor protection, that the offeror not take into account the volume or value of, or condition remuneration on, business or patients not covered under the value-based arrangement. This approach is consistent with our proposal in paragraph 1001.952(ee)(5), as well as the comments summarized above recommending that we limit any volume or value condition to patients who are not part of the value-based arrangement.

However, we also acknowledge commenters' concerns that legitimate care coordination arrangements may naturally involve referrals across provider settings. In this final rule, therefore, we have not finalized a fair market value requirement or a prohibition on determining the amount or nature of remuneration in a manner that takes into account the volume or value of referrals or other business generated. Instead, we have relied on other program integrity safeguards so that the safe harbor will protect beneficial care coordination arrangements while precluding protection for pay-for-referral schemes that do not serve, and may be contrary to, the goals of coordinated care and the shift to value. These safeguards operate to preclude safe harbor protection for abusive arrangements such as a provider churning patients through care settings to capitalize on a reimbursement scheme or otherwise generate revenue and arrangements where VBE participants offer, or are required to provide, remuneration to receive referrals or to be included in a ''preferred provider network'' (*i.e.,* ''pay-to-play'' arrangements).

In response to commenters' concerns that a fair market value requirement would constrain the kinds of care coordination arrangements that we intend to protect, we also are not finalizing a fair market value requirement. However, we have included a commercial reasonableness standard in this safe harbor, which requires that the value-based arrangement be commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE. We believe this commercial reasonableness standard, in combination with the other safe harbor conditions, appropriately balances program integrity concerns and the need to facilitate innovative value-based arrangements.

iv. Additional Requirements for Dialysis Providers

Summary of OIG Proposed Rule: In recognition of the unique attributes of the dialysis industry (*e.g.,* market dominance by a limited number of dialysis providers), we expressed concern in the OIG Proposed Rule that participation by dialysis providers in value-based arrangements could present increased fraud and abuse risks. Accordingly, we solicited comments on potential additional safe harbor conditions specific to dialysis providers to ensure that their care coordination arrangements operate to improve the management and care of patients and are not pay-for-referral schemes. We stated that we were considering including conditions such as enhanced monitoring, reporting, or data submission.

Summary of Final Rule: We are not finalizing additional conditions on dialysis providers in the care coordination arrangements safe harbor.

Comment: Commenters generally opposed additional conditions on dialysis providers on the basis of one or both of the following arguments: (i)

ESRD patients would stand to benefit the most from the care coordination arrangements safe harbor (highlighting, for example, the fact that such patients require care across multiple providers); and (ii) OIG's concerns regarding market consolidation were misplaced. Other commenters stated additional safeguards were not necessary for dialysis providers based on data indicating improved quality of care for ESRD patients and reduction of costs. In contrast, an association representing dialysis providers shared OIG's concerns that the unique characteristics of the highly concentrated dialysis market posed unique and significant fraud and abuse risks and encouraged OIG to develop detailed methodologies and metrics to facilitate OIG's monitoring and assessment of market consolidation and possible pay-for-referral schemes, before permitting dialysis providers to use the value-based safe harbors.

Response: While we are mindful of concerns created by a potential decrease in competition among dialysis providers, we are persuaded that the potential benefits of care coordination within the dialysis community outweigh the concerns for a potential decrease in competition. Accordingly, we are not imposing additional requirements specific to dialysis providers in the care coordination arrangements safe harbor.

v. Submission of Information to Department

Summary of OIG Proposed Rule: To promote transparency, we solicited comments in the OIG Proposed Rule on a requirement, specific to the care coordination arrangements safe harbor, for VBEs to submit certain data to the Department that would identify the VBE, VBE participants, and value-based arrangements.

Summary of Final Rule: We are not finalizing this proposed requirement in the care coordination safe harbor.

Comment: Some commenters strongly supported a requirement for VBEs to submit data to the Department or to a publicly available database that would identify the VBE, VBE participants, and value-based arrangements. A commenter supported an optional reporting requirement and appeared to believe that any such data submission would result in the applicable parties' automatically satisfying the safe harbor's writing requirement.

Other commenters urged OIG not to adopt such a requirement and provided various reasons for their position. For example, some commenters stated that the requirement would be unduly burdensome or that the administrative burden would outweigh any program integrity benefit to the Department, while at least one commenter believed the requirement could discourage implementation of value-based arrangements or full compliance with the safe harbor. Another commenter asserted that a requirement for VBEs to submit certain data to the Department would be unnecessary in light of the proposed requirement for parties to make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of the care coordination arrangements safe harbor. A commenter also expressed concern that the materials and records submitted to the Department could be subject to the Freedom of Information Act and misused by some to gain access to potentially competitive, proprietary information regarding trade secrets, commercial relationships, or value-based arrangement business model information.

Response: To minimize burden, the final care coordination arrangements safe harbor does not require VBEs to submit data to the Department (*e.g.,* data or information relating to the identity the VBE, VBE participants, and value-based arrangements), unless records are requested by the Secretary under the materials and records requirement. OIG will continue to evaluate whether to modify this safe harbor in the future. A better understanding of the structure of VBEs, likely VBE participants, and the form of value-based arrangements could allow for more effective oversight and identification of potential problems. OIG maintains its oversight authorities to conduct audits and evaluations, as well as criminal, civil, and administrative investigations of fraud and misconduct related to Federal health care programs, operations, and beneficiaries. Finally, we remind parties that they must make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of a safe harbor, a required at paragraph 1001.952(ee)(12).

p. Alternative Regulatory Structure

Summary of OIG Proposed Rule: In the OIG Proposed Rule, we stated that we were considering an alternative regulatory structure and approach to protect care coordination and other value-based arrangements that are not at full financial risk and are not part of a CMS-sponsored model.[49] Under the alternative approach, we stated that we would rely on the personal services and management contracts safe harbor at paragraph 1001.952(d) to allow greater flexibility for innovation as arrangements become more closely aligned with value-based purposes and the parties take on more downside financial risk.

Summary of Final Rule: We are not finalizing the alternative regulatory structure.

Comment: Several commenters opposed this alternative regulatory approach. Some argued that it would not provide as clear a mechanism for obtaining safe harbor protection for value-based arrangements as the proposed value-based safe harbors and that a fair market value requirement would create operational challenges. Another commenter asserted that the alternative approach would not provide sufficient protection against fraud and abuse and encouraged OIG to proceed with the proposed value-based safe harbors. Another commenter expressed support for the alternative regulatory structure to the extent OIG did not adopt the value-based exceptions proposed by CMS.

Response: We thank commenters for their insights. While we believe that the alternative approach of creating tiered protection using the personal services and management contracts safe harbor at paragraph 1001.952(d) also would accomplish the objective of allowing greater flexibility for innovation as the arrangements become more closely aligned with value-based purposes and the parties take on more downside financial risk, we concluded that the value-based framework described in section III.B.1 of this preamble is better calibrated to achieve the objectives of the Regulatory Sprint to Coordinated Care. We elected to finalize the value-based framework because we agree with those commenters who stated that the value-based framework would better protect against fraud and abuse, and we were mindful of those commenters who stated that the alternative approach would create operational challenges.

Comment: A commenter suggested that OIG adopt a safe harbor specific to value-based activities undertaken by an integrated delivery system that includes a non-profit payor and a dedicated physician group that includes physician owners and employees. According to the commenter, the remuneration paid among the system's components presents a low risk of fraud and abuse. Another commenter recommended that OIG adopt a safe harbor for a limited set of arrangements that are pre-approved by OIG to promote care coordination and management, reduce costs, or

[49] 84 FR 55715–16 (Oct. 17, 2019).

facilitate a transition to value-based care. According to the commenter, the safe harbor should be limited to specific value-based purposes delineated by OIG, with certification required for any arrangements that have value-based purposes outside those identified by OIG.

Response: We did not propose these suggested safe harbors, and thus, we are not adopting them in this final rule. Depending on the facts and circumstances, remuneration exchanged pursuant to an arrangement between or among parties in an integrated delivery system could be protected under one of the value-based safe harbors we are finalizing in this final rule. With respect to the comment requesting a safe harbor for arrangements that would be pre-approved by OIG and, in certain instances, subject to certification requirements, we believe that such an approach would be administratively unworkable and overly burdensome. Parties who would like to recommend new safe harbors not finalized in this rulemaking may do so by responding to OIG's annual solicitation regarding the development of new or modified safe harbor regulations.[50]

4. Value-Based Arrangements With Substantial Downside Financial Risk (42 CFR 1001.952(ff))

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ff) a safe harbor for certain value-based arrangements involving the exchange of remuneration between a VBE that assumes substantial downside financial risk from a payor and a VBE participant that meaningfully shares in the VBE's downside financial risk. We proposed methodologies for determining substantial downside financial risk and what it means to meaningfully share in risk (discussed further at III.B.4.b). We proposed that the safe harbor would protect both monetary and in-kind remuneration and explained that the safe harbor would offer greater flexibility, compared to the care coordination arrangements safe harbor at paragraph 1001.952(ee), in recognition of the VBE's assumption of substantial downside financial risk. We explained in the OIG Proposed Rule that the safe harbor could apply, for example, to a value-based arrangement between an accountable care organization that is a VBE and a network provider to share savings and losses earned or owed by the accountable care organization, or between a VBE that has contracted with a payor for an episodic payment and a hospital and post-acute care provider that would be coordinating care for the patients under the episodic payment. We proposed additional conditions that would apply under the safe harbor, detailed in sections III.B.4.c–q.

Summary of Final Rule: We are finalizing, with modifications, the requirements of this safe harbor at paragraph 1001.952(ff). For a value-based arrangement to be protected under this safe harbor, a VBE must assume substantial downside financial risk from a payor under one of three methodologies, and a VBE participant must assume a meaningful share of the VBE's total risk, which share has been reduced, under the first methodology, from 8 percent in the proposed rule to at least 5 percent in the final rule. The final provisions governing these levels of risk are discussed at section III.B.4.b of this preamble. The safe harbor, as finalized, protects both monetary and in-kind remuneration exchanged pursuant to value-based arrangements between VBEs and VBE participants. Other conditions finalized in the rule are explained in detail at sections III.B.4.c–q. These conditions include: Ineligible entities; inclusion of a 6-month ''phase-in'' period; requirements that certain remuneration be used to engage in value-based activities and directly connect to certain value-based purposes; writing and record retention requirements; protections for patient choice and clinical decision-making; protections against medically unnecessary services; limits on marketing or patient recruitment; and limits on remuneration that takes into account business or patients outside the value-based arrangement. We are not finalizing the proposed limit on outside funding of protected remuneration. The final safe harbor does not offer protection for arrangements downstream of a VBE participant, such as arrangements between two VBE participants. The final safe harbor permits protection for payments made under the upstream risk-assumption contracts between the VBE and the payor from whom the VBE assumes risk.

The final safe harbor at paragraph 1001.952(ff) may be used by participants in CMS-sponsored models, if safe harbor conditions are met, but it is primarily for other kinds of value-based arrangements, including arrangements in the commercial market. We are separately finalizing a safe harbor at paragraph 1001.952(ii) for CMS-sponsored models (as defined) (see discussion at section III.B.7).

a. General Comments

Comment: While some commenters supported the substantial downside financial risk safe harbor, others expressed concern that the safe harbor is too complicated to be useful.

Response: We appreciate commenters highlighting their concerns. We have revised the substantial downside financial risk safe harbor by streamlining and clarifying its defined terms and conditions, which we believe addresses these concerns. For example, in paragraph 1001.952(ff)(9), we provided additional clarity about the manner in which parties must calculate savings and losses pursuant to methodologies in the definition of ''substantial downside financial risk.''

Comment: Multiple commenters urged OIG to align this safe harbor with CMS's exception to the physician self-referral law for value-based arrangements with meaningful downside financial risk in order to facilitate their compliance efforts. Commenters generally favored the risk thresholds proposed in the meaningful downside financial risk exception to the physician self-referral law over the substantial downside financial risk thresholds proposed in OIG's safe harbor.

Response: As with the OIG Proposed Rule, we coordinated with CMS in the development of this final rule and aimed to promote alignment between the two rules where possible. For a general discussion of the rationale for our decision to finalize safe harbors that diverge in certain aspects from the parallel exceptions to the physician self-referral law, we refer readers to section III.A.1 of the preamble to this final rule. With respect to the risk thresholds in CMS's rule, and as discussed further below, we have determined that CMS's methodology is not appropriate for this safe harbor because it focuses on physician risk arrangements and remuneration rather than risk assumed at the VBE level.

b. Definitions

i. Substantial Downside Financial Risk

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ff)(8)(i) that a VBE would be at substantial downside financial risk if it were subject to risk pursuant to one of four methodologies: (i) Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures; (ii) a

[50] Section 1128D(a) of the Act (42 U.S.C. 1320a–7d(a)).

repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures; (iii) a prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, where such payment is determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures; or (iv) a partial capitated payment from the payor for a set of items and services for the target patient population where such capitated payment reflects a discount equal to at least 60 percent of the total expected fee-for-service payments based on historical expenditures or, to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the value-based arrangements.

Summary of Final Rule: We are finalizing, with modifications, the definition of ''substantial downside financial risk'' at paragraph 1001.952(ff)(9)(i). Based on comments, we are reducing the risk threshold that parties must assume in order to meet the definition of ''substantial downside financial risk'' for the first payment methodology (the ''Shared Savings and Losses Methodology'') to 30 percent, and we are clarifying that, under this methodology, savings and losses must be calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a *bona fide* benchmark designed to approximate the expected total cost of such care. We are clarifying that, for the second methodology, savings and losses must be calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that is covered by the applicable payor to a *bona fide* benchmark designed to approximate the expected total cost of care for the defined clinical episode of care (the ''Episodic Payment Methodology''). We also clarify that, for the Episodic Payment Methodology, the parties must design the clinical episode of care to cover items and services furnished collectively in more than one care setting. We are finalizing a revised partial capitation methodology (the ''VBE Partial Capitation Methodology'') pursuant to which the VBE is at substantial downside financial risk if the VBE receives from the payor a prospective, per-patient payment that is: (i) Designed to produce material savings; and (ii) paid on a monthly, quarterly, or annual basis, for a predefined set of items and services furnished to the target patient population designed to approximate the expected total cost of expenditures for the predefined set of items and services. Finally, we are not finalizing the proposed population-based payment methodology because population-based payments may not, in all circumstances, involve downside financial risk. For example, we understand that at least some population-based payments do not put providers at risk of receiving a lower reimbursement amount and instead are used as a cash-flow mechanism to support provider investments in care management tools.

Comment: Although we received some statements of support, the overwhelming majority of commenters on this topic opposed our proposed definition of ''substantial downside financial risk.'' These commenters generally asserted that our proposed risk thresholds were too high, particularly for the Shared Savings and Losses Methodology and suggested other thresholds, such as 10 percent for the Shared Savings and Losses Methodology. For example, a commenter asserted that our proposed definition of ''substantial downside financial risk'' was not aligned with the levels of risk assumed under other public and private sector value-based payment initiatives and would serve as a barrier to providers entering into risk-based arrangements. The same commenter suggested that, in setting qualifying risk levels too high, OIG would promulgate safe harbors that would be available only to sophisticated entities that are able to take on high levels of financial risk (*e.g.,* ACOs associated with large health systems). Another commenter stated that our identified risk thresholds were arbitrary and biased against smaller and rural health care providers because such providers likely lack the capital reserves necessary to assume substantial downside financial risk. Other commenters asserted that our view of risk was too narrow by failing to consider the importance of upside financial risk, contractual risk, clinical risk related to treating complex patients, operational risk, and investment risk. At least one commenter urged OIG to include financial risk that is assumed only in the event certain quality benchmarks are not met.

Response: We solicited comments on whether the proposed risk thresholds should be higher or lower, or whether some or all of the methodologies should be modified to better capture the assumption of substantial downside financial risk for items and services furnished to patients or omitted from the final rule entirely. In response to comments and based on further consideration of risk assumption requirements used by Innovation Center models, we are reducing the risk threshold required for the Shared Savings and Losses Methodology from 40 to 30 percent, and we are not including a risk threshold in the VBE Partial Capitation Methodology. We are retaining the 20 percent risk threshold for the Episodic Payment Methodology because we believe the risk threshold proposed and finalized is consistent with the design of episodic payment models in which health care stakeholders currently participate, including Innovation Center models that adopt a similar payment methodology. The risk thresholds in the final rule reasonably reflect substantial downside financial risk under the three methodologies for purposes of this safe harbor. Moreover, we believe risk thresholds are necessary to mitigate traditional fraud and abuse risks associated with payment systems that incorporate, in whole or in part, fee-for-service reimbursement methodologies. Arrangements with lower risk levels would be analyzed for compliance with the anti-kickback statute on a fact-specific basis.

The requirement for the VBE to assume substantial downside financial risk, as opposed to upside financial risk, contractual risk, clinical risk related to treating complex patients, operational risk, or investment risk, or financial risk that is assumed only in the event certain quality benchmarks are not met, is appropriate because we are not persuaded that other types of risk would provide as strong an incentive to change ordering or referring behaviors of providers and suppliers that might still be paid on a fee-for-service basis or otherwise help ensure that safe-harbored arrangements would serve appropriate value-based purposes. We believe the risk levels set in the final rule will be substantial enough to reduce any traditional volume-driven incentives to overutilize or increase program costs by ordering and referring providers and to increase incentives to promote efficient delivery of health care.

This safe harbor does not prevent the VBE from assuming other types of risk from the payor suggested by commenters, *e.g.,* investment risk, contractual risk, and clinical risk related

to treating complex patients, as long as the VBE also assumes substantial downside risk from a payor. However, we note that these other types of risk may result in an exchange of remuneration that implicates the Federal anti-kickback statute and must be separately considered for compliance with the statute.

As discussed in section III.B.4.d below, a VBE and a payor that is a VBE participant can enter into value-based arrangements to protect remuneration under this safe harbor. The types of risk suggested by commenters may be protected by this safe harbor if remuneration exchanged and the associated value-based arrangements meet all applicable conditions.

We appreciate the challenges associated with assuming risk that certain smaller and rural providers may face. The definition of ''VBE'' affords parties significant flexibility and places no limit on the number of providers that can participate in the VBE and work together to assume substantial downside financial risk. We also highlight that other safe harbors, including the care coordination arrangements safe harbor, at paragraph 1001.952(ee), and the outcomes-based payments safe harbor at paragraph 1001.952(d)(2), may be available for parties that are not ready to assume the level of risk required by this safe harbor.

Comment: Commenters requested clarification on the practical application of the methodology OIG proposed in the ''substantial downside financial risk'' definition—shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses. For example, a commenter asked whether the shared savings and losses repayment calculation must be applicable to the entire value-based enterprise or if it could be limited to a particular shared savings and losses arrangement between specified VBE participants. Other commenters asked whether the shared savings and losses repayment obligation could be in the form of a forfeited withhold or risk-pool payment, as opposed to an actual repayment of cash. Similarly, another commenter asserted that this methodology should permit the assumption of risk through front-end withholds or dues assessments. Another commenter asked how the shared savings and losses percentage threshold should be calculated if the sharing rate varies based on quality performance and other adjustments.

Response: In response to commenters' request for additional detail, we are clarifying that the Shared Savings and Losses Methodology expressly requires that any losses and savings calculations take into account *all* items and services that are covered by the applicable payor and furnished to the target patient population, not simply those items and services furnished by specified VBE participants. In other words, the Shared Savings and Losses Methodology is dependent on the items and services covered by the payor and provided to the target patient population, not the specific composition of the VBE and its VBE participants. For example, a VBE could not limit its risk for shared savings and losses under this methodology for certain outpatient items and services by only entering into value-based arrangements with a narrow set of providers that only furnish care in outpatient settings.

In response to comments, we also are clarifying that this methodology permits the assumption of risk prospectively or retrospectively. As long as the VBE meets the requirements of the Shared Savings and Shared Losses Methodology, as finalized, including the requirement that losses and savings be calculated by comparing certain expenditures to a *bona fide* benchmark designed to approximate the expected total cost of the applicable care, this safe harbor does not prescribe how the payor and VBE structure payments to effectuate the VBE's risk.

Finally, under the Shared Savings and Losses Methodology, financial risk must equal at least 30 percent of loss, where loss is determined by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a *bona fide* benchmark designed to approximate the expected total cost of such care. To satisfy the Shared Savings and Losses Methodology, any adjustments based on quality performance or other factors may not bring the financial risk below 30 percent of such loss.

Comment: With respect to the second proposed methodology (the Episodic Payment Methodology), some commenters asked whether such arrangements could be prospective or retrospective. A commenter asserted that we should add another episodic or bundled payment arrangement methodology, similar to this methodology, but that requires any repayment obligation for losses to equal, at a minimum, 20 percent of historical expenditures. The commenter also requested that we clarify that this methodology applies only to an ''episode of care'' that involves multiple care settings. Finally, a commenter, asserting that it was unaware of any value-based arrangement that can provide quality care at 80 percent of episode costs, recommended we reframe this substantial downside financial risk methodology as ''discount-based.''

Response: As an initial matter, we clarify that the Episodic Payment Methodology is with respect to a set of defined items and services related to a clinical condition and, as a result, have replaced the OIG Proposed Rule term ''episodic or bundled payment methodology'' with ''clinical episode of care'' in order to better convey this requirement. We also confirm that financial risk assumed pursuant to the Episodic Payment Methodology may be prospective or retrospective.

In response to the commenter that requested we clarify that this methodology applies only to an ''episode of care'' that involves multiple care settings, we are requiring in paragraph 1001.952(ff)(9)(i)(B)(2) that the parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting. The VBE and the payor can meet this requirement as long as they design the clinical episode of care to cover a collection of items and services that they anticipate will be provided in more than one care setting even if a particular patient in the target patient population undergoing a clinical episode of care ultimately does not receive items and services in more than one care setting. We believe this requirement is consistent with episodic or bundled payment methodologies that involve services delivered by more than one provider and promotes collaboration across providers and suppliers that may otherwise operate independently and deliver care in silos.

To illustrate these clarifications, the Episodic Payment Methodology could include a clinical episode of care for an inpatient procedure for which the payor and the VBE design the clinical episode of care to cover items and services furnished across care settings in a hospital and post-acute care setting, such as a physician clinic or a skilled nursing facility. In contrast, we do not consider a bundled payment to a provider for an episode of care that occurs in a single setting, such as a DRG payment to a hospital for inpatient services, to be an episodic payment for purposes of this rule.

Lastly, we are not finalizing an episodic payment methodology that requires a repayment obligation for losses equal to, at a minimum, 20 percent of historical expenditures or reframing the Episodic Payment Methodology as ''discount based,'' as suggested by a commenter. We clarify that the Episodic Payment Methodology,

as finalized, does not require the payor to discount the cost of items and services included in the defined clinical episode of care by 20 percent. Rather, the VBE must assume risk for at least 20 percent of any *loss* realized pursuant to a defined clinical episode of care, with losses (and savings) calculated by comparing current expenditures for all items and services included in the defined clinical episode of care and furnished to the target patient population to a *bona fide* benchmark designed to approximate the expected total cost of such care.

Comment: Commenters generally expressed confusion regarding the application of the fourth prong included in the proposed ''substantial downside financial risk'' definition—a partial capitation payment that reflects a discount equal to at least 60 percent of the total expected fee-for-service payments. For example, a commenter asked why this methodology includes a discount because capitation itself places a physician at risk through a per-member, per-month payment. Another commenter suggested that we revise this prong to encompass capitated payments for a limited set of services, *e.g.,* primary care. Some commenters asserted that the 60 percent discount level was not economically feasible and suggested that OIG lower the discount level.

Response: In response to comments, we are finalizing the VBE Partial Capitation Methodology, with modifications. We are removing the discount percentage requirement in recognition that the partial capitation payment, as set forth in paragraph 1001.952(ff)(9)(i)(C), itself, constitutes the assumption of substantial downside financial risk. In keeping with the intent of the prior discount percentage requirement, we also are requiring that this methodology be designed to result in material savings. In other words, the VBE Partial Capitation Methodology is designed to achieve cost efficiencies by incentivizing better care coordination that benefits patients and the health care delivery system by placing the VBE at substantial downside financial risk.

We are not defining material savings in regulatory text to provide parties flexibilities in designing partial capitation payments. There are a number of ways that parties might design a partial capitation payment consistent with this methodology to generate material savings. For example, the parties may design a capitation payment with utilization targets that are intended to lower costs versus historical utilization, or the parties may use other methodologies that incentivize the VBE to operate more efficiently and lower costs. We recognize that, as the VBE and its VBE participants become more efficient, the opportunity to achieve materials savings, as that term is commonly understood, may become more difficult. As a VBE successfully reduces costs in one year, it becomes harder to further reduce costs in subsequent years. Under this methodology, and because we are not defining ''material savings,'' parties have flexibility to design partial capitation payment rates to account for such issues. For example, the parties could use national or regional utilization data in designing the partial capitation payment to appropriately adjust the payment rates to account for the efficiency of the VBE.

Additionally, given the complexity of establishing a partial capitation payment, payors, from whom the VBE assumes risk under this methodology, will have a significant role in their design. Payors have experience and expertise in designing actuarial models to assess and project costs for their plans and establish rates. Capitation payments designed consistent with generally accepted actuarial principles can, for example, ensure that a partial capitation payment: (i) Captures all reasonable, appropriate, and attainable costs; (ii) is sufficient, based on past and anticipated service utilization by the target patient population; (iii) reflects cost trends; (iv) is risk adjusted as appropriate; and (iv) provides documentation and transparency on how the rate was developed. While not an exhaustive list, these factors would be relevant in assessing whether a capitation payment is designed to generate material savings.

We also are clarifying the form in which the VBE must receive a partial capitation payment. Specifically, we are requiring that the VBE receive from a payor a prospective, per-patient payment, paid on a monthly, quarterly, or annual basis. This methodology would not include fee-for-service payments under the Medicare inpatient prospective payment system or other fee-for-service payments under Medicare Parts A or B. The per-patient payment must be for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services. As noted above, this payment must be intended to result in material savings.

We emphasize that, under the VBE Partial Capitation Payment Methodology, the VBE is assuming risk for a predefined set of items or services that are less than all of the items and services covered by the payor, in contrast to the full financial risk safe harbor, which requires the VBE to assume full financial risk for all items and services from a payor. For example, a partial capitation payment under this methodology may cover primary care services only for a target patient population but not inpatient services, prescription drugs, or other items and services covered by the payor.

While we are not specifying a percentage or scope of items and services that must be reimbursed on a capitated basis, the requirement that partial capitation payments be intended to result in material savings achieves a similar purpose. A VBE assuming substantial downside risk is afforded flexibility under this safe harbor because, as explained previously, this level of risk mitigates the traditional risks of fraud and abuse associated with fee-for-service payments. The effectiveness of that mitigation is directly connected to the incentive associated with substantial downside risk methodologies; increased risk means the VBE has a greater incentive to reduce costs and improve outcomes for patients. In the context of the VBE Partial Capitation Methodology, the substantial downside risk is partly dependent on the scope of items and services covered by the partial capitation payment. For example, a VBE that receives a partial capitation payment for inpatient services associated with one DRG has less incentive than a VBE that receives a partial capitation payment for all inpatient services.

We recognize that payors are unlikely to contract with a VBE under a partial capitation payment for a narrow set of items or services. However, ensuring that VBEs have the appropriate level of incentives by assuming risk is a key safeguard in this safe harbor and is the reason why we are finalizing the requirement that partial capitation payments be designed to generate material savings. We note that the scope of services is just one factor for determining whether the capitation payment was designed to generate material savings. For example, a VBE and a payor could design a partial capitation payment that meets this methodology if the VBE receives capitation payments for a narrow set of services that are typically high cost as long as the capitation payments for that limited set of high-cost items or services were designed to generate material savings.

We also note that this safe harbor conditions protection on the VBE assuming substantial downside

financial risk from the payor for the predefined items and services. It does not require the VBE to assume other functions from the payor, such as enrollment, grievance and appeals, solvency standards, and other administrative functions performed by payors.

Comment: In response to our solicitation of comments regarding alternative means to calculate savings and losses (and in particular, how best to establish a baseline that appropriately assesses the VBE's financial performance), we received a number of comments recommending modifications to the proposed requirement that, for each methodology under the ''substantial downside financial risk'' definition, parties would need to determine any savings or losses realized based upon a review of historical expenditures, or to the extent such data was unavailable, evidence-based, comparable expenditures. For example, several commenters questioned our reliance on historical expenditures as a reliable datapoint, with several expressing concern that such a standard may not be adequately risk-adjusted or an accurate benchmark to the extent parties are providing new treatments, items, and services (representing the latest advances in technology, for example) that exceed the cost of treatment in benchmark years. At least two commenters recommended that we add ''projected spending'' as a method to compare costs, with one asserting that historical expenditures may not be appropriately risk adjusted. A commenter also suggested that we allow parties to adjust payments as needed to cover the costs of new treatment options.

Response: We are no longer requiring that parties rely on historical expenditures or evidence-based, comparable expenditures to determine a benchmark used in calculating any losses or savings realized. We recognize, as highlighted by commenters, that historical expenditures could be volatile or otherwise result in an inaccurate benchmark, particularly for smaller entities, and that other data, such as national or regional data, may be appropriate factors that can be used for setting an accurate benchmark. Consequently, we are revising this requirement to provide that, for two of the methodologies finalized in the ''substantial downside financial risk'' definition—the Shared Savings and Losses Methodology and the Episodic Payment Methodology—parties must calculate any losses or savings based upon a *bona fide* benchmark, *i.e.,* a legitimate benchmark, designed to approximate the cost of care.[51] Specifically, for the Shared Savings and Shared Losses Methodology, we require that the parties calculate losses by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a *bona fide* benchmark designed to approximate the expected total cost of such care. Similarly, for the Episodic Payment Methodology, we require that parties calculate losses by comparing current expenditures for all items and services that are covered by the applicable payor, furnished to the target patient population, and relate to a defined clinical episode of care to a *bona fide* benchmark designed to approximate the expected total cost of care for the defined clinical episode of care.

This revision has two aims. First, we seek to protect against the selection of benchmarks that artificially create savings or inappropriately insulate any VBE participant from losses. This is based on our intent to ensure that parties are truly assuming downside financial risk. Second, we seek to provide parties with the flexibility necessary to establish a baseline tailored to the contract or value-based arrangement between the VBE and the payor. Thus, under these revised methodologies, a *bona fide* benchmark does not need to be based on historical expenditures or, to the extent such data is unavailable, evidence-based, comparable expenditures, as proposed in the OIG Proposed Rule. With this revised standard, a *bona fide* benchmark may be appropriately adjusted, *e.g.,* through a prospective or retrospective risk-adjustment to account for outlier health care expenditures, provided the methodology for such adjustment is established in advance. We emphasize that any such adjustment must be consistent with the requirement that the *bona fide* benchmark be designed to approximate the expected total cost of care.

We note that there are several ways that parties may demonstrate that a benchmark is *bona fide.* Parties seeking examples of *bona fide* benchmarks may look to Innovation Center models, the Medicare Shared Savings Program, Medicaid programs, or private payors that have adopted and validated benchmarks for their participants in similar risk-based models. *Bona fide* benchmarks may incorporate concepts such as risk adjustments, cost projections (including those related to new treatments), and peer comparisons, as applicable. Given the complexity of establishing a benchmark, we anticipate that payors from whom the VBE assumes risk will be involved in their design. Similar to the design of a partial capitation payment, payors have relevant experience and expertise in designing actuarial models to assess and project costs for their plans that will support the development of *bona fide* benchmarks. Benchmarks that are validated or designed consistent with generally accepted actuarial principles will likely be *bona fide.* Parties will need to assess and ensure the validity and appropriateness of the benchmark based on the specific facts and circumstances of their VBE, the value-based arrangement, the scope of the items and services covered, and the target patient population.

Comment: Several commenters requested that OIG include a cap or stop-loss threshold in the substantial downside financial risk safe harbor that would limit the amount of loss incurred by the VBE. For example, specific to the clinical episode of care methodology, a commenter recommended that we limit potential losses to 20 percent of historical expenditures; specific to the shared savings methodology, a commenter encouraged protection for arrangements that include stop-loss thresholds for shared losses set at a certain percentage of historical benchmark costs, akin to the Medicare Shared Savings Program.

Alternatively, other commenters urged OIG to simply clarify that reinsurance arrangements, or other like arrangements to protect against catastrophic losses, would not fall outside of our proposed definition of ''substantial downside financial risk.'' According to these commenters, reinsurance arrangements are critical to encouraging the assumption of downside financial risk.

Response: Given the inherent differences in target patient populations, the sophistication of parties participating in value-based arrangements, and varying risk methodologies that parties may adopt, we decline to include a specific cap, stop-loss threshold, or reinsurance threshold. This provides parties

[51] We are not requiring that parties compare current expenditures to a *bona fide* benchmark designed to approximate the expected total cost of care for the VBE Capitation Payment Methodology because of its prospective nature and per-patient, per-month, per-quarter, or per-year payment structure. Instead, for this methodology, parties must establish a capitated payment for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services. The capitated payment must also (among other criteria) be intended to result in material savings.

flexibility to adopt various risk methodologies that still satisfy the safe harbor's definition of ''substantial downside financial risk.'' Parties entering into a contract or a value-based arrangement to assume substantial downside financial risk should have the flexibility to determine the appropriate cap, stop-loss, or reinsurance threshold, if any, and we clarify that neither the safe harbor's conditions nor the definition of ''substantial downside financial risk'' precludes parties from entering into reinsurance arrangements or other like arrangements to protect against catastrophic losses. Nevertheless, we caution that such arrangements should not be used as a vehicle to materially shift the substantial downside financial risk a VBE is otherwise required to assume pursuant to this safe harbor.

Comment: Several commenters supported OIG's alternate proposal to adopt risk levels more closely aligned with advanced APMs and other payor advanced APMs, as both terms are defined at 42 CFR 414.1305, or requested that the definition of ''substantial downside financial risk'' include advanced APMs. In addition, a commenter noted that the risk levels proposed by OIG exceeded those required in advanced APMs.

Response: We are not revising the risk levels set forth in the ''substantial downside financial risk'' definition to align with those of advanced APMs and other payor advanced APMs, as both terms are defined at 42 CFR 414.1305. Different risk thresholds between this safe harbor and advanced APMs and other payor advanced APMs are appropriate in light of the differing objectives between this rulemaking and the Quality Payment Program, the Medicare payment program that relies on the defined terms advanced APMs and other payor advanced APMs. For example, the advanced APM track of the Quality Payment Program is specific to eligible clinicians and offers a potential five percent Medicare bonus payment, among other benefits. By contrast, this safe harbor protects arrangements of a wide variety of industry stakeholders beyond eligible clinicians from liability under a criminal statute and sets out the conditions under which that protection is available.

It is possible that participants in an advanced APM might assume risk at levels that meet the requirements of this safe harbor. Further, some advanced APM participants may be eligible for safe harbor protection under the new CMS-sponsored model arrangements safe harbor found at paragraph 1001.952(ii).

Comment: Multiple commenters requested that we opine on whether certain arrangements would meet our proposed definition of ''substantial downside financial risk.'' For example, at least two commenters requested that we address whether a bonus pool or gainsharing arrangement, tied to the achievement of certain outcome measures, could potentially meet our definition of ''substantial downside financial risk.'' The commenters argued in favor of such an interpretation, asserting that the potential to earn a bonus payment constitutes downside risk to the extent the bonus is (i) otherwise considered part of the recipient's aggregate compensation, and (ii) withheld if outcome measures are not met.

Response: The definition of ''substantial downside financial risk'' requires, among other criteria, that the VBE assume the potential for realizing losses. This definition would permit parties to design a two-sided risk methodology that would place the VBE at downside financial risk and upside financial risk. In other words, the definition requires, at a minimum, the VBE to assume substantial downside financial risk, but does not preclude the parties from including other risk methodologies, so long as all other conditions of the safe harbor are met. For example, arrangements that include a bonus pool or gainsharing, along with the VBE assuming the required substantial downside financial risk, may be protected by this safe harbor. However, a risk methodology that only includes upside risk would not meet this requirement.

ii. Meaningful Share

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ff)(2) that this safe harbor would protect remuneration exchanged between a VBE and a VBE participant if the VBE participant meaningfully shares in the VBE's substantial downside financial risk for providing or arranging for items and services for the target patient population. We proposed that a VBE participant would meaningfully share in the VBE's risk if the VBE participant met one of the following three methodologies: (i) A risk-sharing payment pursuant to which the VBE participant is at risk for 8 percent of the amount for which the VBE is at risk under its agreement with the applicable payor (*e.g.,* an 8-percent withhold, recoupment payment, or shared losses payment); (ii) a partial or full capitated payment or similar payment methodology (excluding certain enumerated reimbursement methodologies); or (iii) in the case of a VBE participant that is a physician, a payment that meets the requirements of the physician self-referral law's regulatory exception for value-based arrangements with meaningful downside financial risk at 42 CFR 411.357(aa)(2).

Summary of Final Rule: We are finalizing, with modifications, at paragraph 1001.952(ff)(3) a requirement for the VBE participant to be at risk for a meaningful share of the VBE's substantial downside financial risk for providing or arranging for the provision of items and services for the target patient population. We are finalizing, with modifications, the proposed definition of ''meaningful share'' at paragraph 1001.952(ff)(9)(ii). Specifically, based on comments we are: (i) Revising the first methodology of the ''meaningful share'' definition (the ''Risk-Sharing Payment Methodology'') to clarify that any risk assumed by a VBE participant pursuant to this methodology must be two-sided risk; (ii) lowering the risk threshold for the Risk-Sharing Payment Methodology from 8 percent to at least 5 percent of the losses and savings, as applicable, realized by the VBE pursuant to its assumption of substantial downside financial risk; (iii) revising the second methodology of the ''meaningful share'' definition to apply to prospective, per-patient payments for a predefined set of items and services furnished to the target patient population (the ''Meaningful Share Partial Capitation Methodology''); and (iv) not finalizing the proposed methodology applicable to physician payments that meet the requirements of the physician self-referral law's regulatory exception for value-based arrangements with meaningful downside financial risk at 42 CFR 411.357(aa)(2) (the ''CMS Exception Methodology'').

Comment: While we received comments in favor of our proposed requirement for the VBE participant to assume a meaningful share of the VBE's substantial downside financial risk, many advocated against it, suggesting no or optional risk requirements for VBE participants downstream from the VBE assuming substantial downside financial risk. These commenters highlighted varying Innovation Center models that do not require the downstream assumption of risk.

Response: We are finalizing a requirement for VBE participants, other than the payor from which the VBE is assuming risk, to be at risk for a meaningful share of the VBE's substantial downside financial risk pursuant to a value-based arrangement

with the VBE. This safe harbor is not chiefly designed for Innovation Center models, which may not have downside financial risk, and which may fit more readily in the new safe harbor at paragraph 1001.952(ii) for CMS-sponsored models. The requirement to assume a meaningful share of the VBE's risk is foundational to the structure of the safe harbor, which does not include certain established safeguards, such as a fair market value requirement, designed to mitigate risks inherent to a traditional fee-for-service payment methodology, nor additional safeguards present in the care coordination arrangements safe harbor, such as a bar on monetary compensation or a contribution requirement, that protect against payment for referral schemes. The requirement to assume a meaningful share of the VBE's risk helps ensure that VBE participants ordering or arranging for items and services for the target patient population share in the VBE's value-based purposes and cost-reduction goals.

The payor from which the VBE is assuming substantial downside financial risk is exempt from the requirement to meaningfully share in the VBE's substantial downside financial risk in paragraph 1001.952(ff)(3). As discussed in greater detail in section III.B.4.d, this carve-out applies to those payors from which VBEs are assuming risk that elect to also be a VBE participant and enter into a value-based arrangement with a VBE. In such circumstances, the payor, as a VBE participant, need not share again in the risk that the VBE assumed from it in the value-based arrangement.

Comment: While at least one commenter supported the risk threshold in the first proposed methodology for meaningfully sharing in the VBE's risk (a risk-sharing payment pursuant to which the VBE participant is at risk for 8 percent of the amount for which the VBE is at risk under its agreement with the applicable payor), the majority of commenters advocated that we lower the risk threshold, such as to 5 percent. Commenters highlighted varying Innovation Center models that impose lower risk requirements or rely on a broader risk framework. Other commenters suggested that this methodology should be expanded to encompass other types of risk, for example, operational or contractual risk. Commenters suggested that a more expansive methodology would encourage a greater number of providers to take on downside risk arrangements while still effectively deterring potential fraudulent behavior. A commenter recommended that OIG revise the first proposed methodology for meaningfully sharing in the VBE's risk to state that the VBE participant is at risk for ''*at least* 8 percent'' of the VBE's risk to allow for other arrangements that involve greater downside risk.

Response: We are revising the Risk-Sharing Payment Methodology to reduce the required minimum risk threshold from 8 percent to at least 5 percent and requiring two-sided risk (*e.g.,* savings and losses). We believe this level of risk is appropriate to ensure VBE participants share the VBE's goal of cost reduction and to reduce fraud and abuse risks while making this safe harbor more accessible to individuals and entities that want to exchange remuneration with the VBE pursuant to this safe harbor. As finalized, this methodology aligns with the Shared Savings and Losses Methodology in the definition of ''substantial downside financial risk.'' This modification will provide VBE and VBE participants additional flexibilities to align risk-sharing methodologies and protect similar exchanges of remuneration (*e.g.,* savings and losses) in value-based arrangements.

We are not permitting VBE participants to meet the Risk-Sharing Payment Methodology by assuming other types of risk, such as operational or contractual risk. We are concerned these types of risk would not adequately align a VBE participant's financial incentives with that of the VBE's cost-reduction goals resulting from the VBE's assumption of substantial downside financial risk.

Comment: Some commenters opposed pegging the first risk-sharing payment methodology of the ''meaningful share'' definition to the total risk assumed by the VBE. For example, a commenter noted that VBE participants, and in particular smaller providers, are unlikely to accept risk for 8 percent of the total amount for which the VBE is at risk from the payor. The commenter urged OIG to revise its meaningfully share standard to require that the VBE participant assume risk only for its own costs and suggested 20 percent as a potential risk assumption threshold.

Response: As finalized, the Risk-Sharing Payment Methodology continues to require that the VBE participant share in a certain percentage of the VBE's total risk. However, in response to comments, we are finalizing a lower risk threshold of 5 percent for this methodology and clarifying that this methodology requires two-sided risk.

We also clarify that, to the extent a VBE realizes catastrophic losses, triggering any reinsurance or other like arrangement into which the VBE has entered, the VBE participant would calculate any amount owed to the VBE pursuant to this methodology based on the VBE's losses, as adjusted by the reinsurance or other like arrangement.

Comment: A commenter requested that OIG define ''partial capitation arrangements'' in the context of the second proposed methodology for meaningfully sharing in the VBE's risk—a partial or full capitation payment or similar payment methodology, excluding the Medicare inpatient prospective payment system or other like payment methodology. The commenter also asked whether there is a minimum amount that would qualify as partial capitation.

Response: In response to comments, we are finalizing the Meaningful Share Partial Capitation Methodology with revisions that, for clarity, more fully describe the permissible capitation methodology. Pursuant to this revised methodology, a VBE participant must: (i) Receive from the VBE a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population by the VBE participant designed to approximate the expected total cost of those expenditures for the predefined items or services; and (ii) not separately claim payment from the payor for the predefined set of items and services covered by the partial capitated payment. Consistent with our stated goal in the OIG Proposed Rule, we believe this methodology ensures that those VBE participants assuming a meaningful share of the VBE's risk pursuant to the Meaningful Share Partial Capitation Methodology do so in a manner that is aligned with the payor's cost-reduction goals.

For the same reasons we are not specifying the percentage or scope of items and services that must be included in the VBE Partial Capitation Methodology, we are not specifying a minimum amount of items and services that must be covered to meet the Meaningful Share Partial Capitation Methodology. Likewise, we note that this methodology would not include fee-for-service payments under the Medicare inpatient prospective payment system or other fee-for-service payments under Medicare Parts A or B. Payments must be made on a monthly, quarterly, or annual basis to satisfy this methodology.

A VBE participant may be at risk through this methodology not only where the VBE is at substantial downside financial risk through the VBE Partial Capitation Methodology but

also any other substantial downside financial risk methodology. For example, VBE participants could be at risk through the Meaningful Share Partial Capitation Methodology, and the VBE could assume substantial downside financial risk from a payor through the Episodic Payment Methodology.

Comment: We received varying comments on the third proposed methodology for meaningfully sharing in the VBE's risk: Physician VBE participants would be deemed to meaningfully share in the VBE's risk if they meet the definition of ''meaningful downside financial risk'' under the physician self-referral law at 42 CFR 411.357(aa)(2). Some commenters either opposed this provision altogether or advocated for a lower threshold than the 25 percent threshold for sharing in the costs of the remuneration exchanged under a value-based arrangement, with a few commenters suggesting between 5 and 15 percent. On the other hand, some commenters supported this provision stating, for example, that it facilitated alignment across OIG's and CMS's rules. Another commenter requested that OIG amend this provision to apply more broadly to other VBE participants and not just physicians.

Response: We are not finalizing the third proposed methodology (the CMS Exception Methodology). Pursuant to the final meaningful downside financial risk exception at 42 CFR 411.357(aa)(2), a physician must be at ''meaningful downside financial risk'' for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement. A physician assumes ''meaningful downside financial risk'' if the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives (or is entitled to receive) under the value-based arrangement in the event of the failure to achieve the value-based purpose(s) of the value-based enterprise.

Upon further consideration of the varied comments we received regarding the CMS Exception Methodology, we believe the CMS Exception Methodology does not fit within the framework of the substantial downside financial risk safe harbor, which is different from the meaningful downside financial risk exception CMS is finalizing. Unlike CMS's meaningful downside financial risk exception, OIG's safe harbor requires the VBE participant to assume risk for a meaningful share of the VBE's substantial downside financial risk. Risk under the CMS Exception Methodology is tied to a percentage of the total value of the remuneration the physician receives under the value-based arrangement rather than a percentage of the risk the VBE assumes from the payor. The CMS Exception Methodology does not require the physician to meaningfully share in financial risk assumed by the VBE, a requirement of the safe harbor.

Comment: A commenter expressed concern that the differing standards for the assumption of downside risk in the safe harbor (*i.e.,* ''substantial downside financial risk'' and ''meaningfully sharing in the VBE's substantial downside financial risk'') would confuse parties to value-based arrangements and discourage participation. The commenter appeared to suggest that OIG adopt a single, low risk threshold in the substantial downside financial risk safe harbor.

Response: While we appreciate the commenter's input, we respectfully disagree. It is appropriate to have differing risk assumption requirements for the VBE and the VBE participant. The VBE is contracting or entering into a value-based arrangement with a payor to assume substantial downside financial risk, most likely for items and services provided across care settings and by multiple VBE participants. Conversely, the VBE participant contracting with the VBE is not only one step removed from the payor contract, but its performance of value-based activities is likely to have a narrower focus, specific to the items and services it furnishes to the target patient population. As such, we believe a lower risk assumption threshold is appropriate for the VBE participant.

Comment: A commenter recommended that ''advanced APMs'' and ''other payer APMs,'' as both terms are defined at 42 CFR 414.1305, should be expressly included in the safe harbor and automatically qualify as assuming a meaningful share of the VBE's substantial downside financial risk. Another commenter suggested that we adopt the ''more than nominal risk'' standard for advanced APMs instead of the proposed ''meaningfully share'' standard.

Response: Because this safe harbor has broader applicability to the health care industry than the regulations in which the defined terms referenced by the commenter are used (which apply to a Medicare payment program for physicians), we decline to revise the definition of ''meaningful share'' to encompass the potentially lower risk thresholds set forth in the ''advanced APM'' and ''other payer APM'' definitions as set forth in 42 CFR 414.1305 or adopt, in lieu of ''meaningful share,'' the ''more than nominal risk'' standard. Thus, participants in advanced APMs and other payer APMs will not automatically qualify as having a ''meaningful share'' of the VBE's substantial downside financial risk and must meet the risk thresholds we are finalizing.

Comment: A commenter asked whether a VBE participant could join an existing value-based arrangement between a VBE and one or more VBE participants and satisfy the safe harbor requirement to assume a meaningful share of the VBE's risk by sharing in such risk only for the duration of its participation in the value-based arrangement, as opposed to the duration of the value-based arrangement.

Response: If the VBE has already entered into a value-based arrangement with one or more VBE participants for purposes of this safe harbor, a party may join the existing value-based arrangement as a VBE participant provided all safe harbor requirements are met, including amending the signed writing to include a description of the manner in which the new VBE participant will have a meaningful share of the VBE's substantial downside financial risk.

We note that, other than during the 6-month phase-in period that is available under this safe harbor, the VBE participant must be at risk for a meaningful share of the VBE's risk throughout its participation in the value-based arrangement. This requirement does not apply if the VBE participant is the payor from which the VBE is assuming risk.

Comment: A commenter asserted that OIG should add language to the safe harbor stating that VBE participants' meaningful share of risk can be through front-end withholds or dues assessments and need not be through back-end repayment.

Response: For the risk methodologies under the definition of ''meaningful share,'' we did not propose, and the final rule does not prescribe, how the parties to a value-based arrangement may effectuate the VBE participant's risk, and as such, the parties could effectuate risk prospectively or retrospectively.

iii. Other Defined Terms

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ff)(8)(ii) that the terms ''coordination and management of care,'' ''target patient population,'' ''value-based activity,'' ''value-based arrangement,'' ''value-based enterprise,'' ''value-based purpose,'' and ''VBE participant'' would

have the meaning set forth in proposed paragraph 1001.952(ee).

Summary of Final Rule: We are finalizing, with modifications, our proposed use of the value-based terminology at paragraph 1001.952(ff)(9)(iii). We no longer use the term ''coordination and management of care'' in this safe harbor. Additionally, because we are finalizing at paragraph 1001.952(ff)(1) a requirement making certain entities ineligible to use the safe harbor, we adopt for this safe harbor the definition of ''manufacturer of a device or medical supply'' at paragraph 1001.952(ee)(12).

Comment: A few commenters requested that OIG define the term ''payor,'' with a commenter specifically suggesting that we define such term to include a managed care organization that has a contract with Medicare, Medicaid, or another Federal health care program that is subject to 1128B of the Act. A commenter also asked OIG to define the term ''used'' in relation to the requirement that remuneration be used primarily to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk and that are set forth in writing. The commenter also asked OIG to define the term ''offeror's cost'' in relation to the requirement that the writing state all material terms of the value-based arrangement, including the offeror's cost of the remuneration.

Response: We are not defining the term ''payor.'' The term has its commonsense meaning of a payor of health care items and services on behalf of patients. We confirm that, for purposes of this safe harbor, such term would include managed care organizations that have contracted with Medicare, Medicaid, and other Federal health care programs. We also are not defining the term ''used'' in regulatory text but use the term consistent with its commonsense, well-understood meaning (*e.g.,* to put into action or service, utilize). Further, we decline to define the term ''offeror's costs'' because, as explained at section III.B.4.k, we are not finalizing the requirement that the writing include the offeror's costs.

c. Entities Ineligible for Safe Harbor Protection

Summary of OIG Proposed Rule: We proposed in proposed paragraph 1001.952(ee) to limit the entities that could qualify as VBE participants, which would have the effect of limiting availability of the value-based safe harbors, including the substantial downside financial risk safe harbor at proposed paragraph 1001.952(ff), for those ineligible entities. The proposed definition of ''VBE participant'' is summarized more fully in section III.B.2.e of this preamble.

Summary of OIG Final Rule: As explained at section III.B.2.e, we are not finalizing our proposal in proposed paragraph 1001.952(ee) to limit the entities that could qualify as VBE participants. Rather, in the final rule we are identifying parties ineligible to rely on safe harbors in the safe harbors themselves. For the substantial downside financial risk safe harbor, we are finalizing a requirement that remuneration is not exchanged by any of the following entities: (i) Pharmaceutical manufacturers, wholesalers, and distributors; (ii) PBMs; (iii) laboratory companies; (iv) pharmacies that primarily compound drugs or primarily dispense compounded drugs; (v) manufacturers of devices or medical supplies; (vi) entities or individuals that manufacture, sell, or rent DMEPOS (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible); and (vii) medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies.

Summaries of comments, our responses, and policy decisions regarding this issue can be found in the discussion of VBE participants in section III.B.2.e of this preamble.

d. VBE's Assumption of Risk From a Payor

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ff)(1) that the VBE must assume substantial downside financial risk from a payor and that the VBE could assume such risk directly from a payor or through a VBE participant acting on behalf of the VBE (*i.e.,* as an agent of, and accountable to, the VBE).

Summary of Final Rule: We are finalizing, with modifications, this requirement at paragraph 1001.952(ff)(2). First, we are modifying the safe harbor to provide two options to VBEs assuming substantial downside financial risk from a payor. A VBE can assume risk from the payor through an arrangement that meets the definition of ''value-based arrangement,'' or a VBE can assume risk from a payor through a contract that places the VBE at substantial downside financial risk. The first option provides protection for the remuneration exchanged between the payor and the VBE, if all safe harbor requirements are met. To effectuate this, the payor must be a VBE participant and the VBE must assume risk from the payor through a value-based arrangement. Under the second option, if a payor does not wish to be part of the VBE, the VBE can assume substantial downside financial risk from the payor through a written contract. Under this option, the contract that places the VBE at risk is not a value-based arrangement and the safe harbor would not protect remuneration exchanged pursuant to it.

Second, we are modifying the risk assumption requirement to clarify that the payor cannot act on behalf of the VBE; the VBE must be a distinct legal entity or represented by a VBE participant, other than a payor, that acts on the VBE's behalf.

Comment: Some commenters opposed the proposed requirement that a VBE assume risk from a payor, asserting payor involvement should not be a prerequisite to safe harbor protection. For example, a post-acute-care provider asserted that, where the financial risk shared between providers is significant, the safe harbor should be available regardless of whether a payor is directly involved.

Response: We are finalizing the requirement that the VBE assume substantial downside financial risk from a payor because we view it as a critical safeguard against the potential for fraud and abuse. Payors are ultimately responsible for the cost of the items and services furnished to a target patient population, which informs our decision to require that they be party to the risk arrangement that serves as the foundation for this safe harbor. Moreover, the payor serves as an entity with both a holistic view of, and a financial interest in reducing, total expenditures for the target patient population, which we believe mitigates the risks traditionally associated with fee-for-service systems, such as overutilization or inappropriate utilization.

Consistent with our emphasis in the OIG Proposed Rule that parties assuming substantial downside financial risk have more flexibility, we have modified the safe harbor so that payors and VBEs have two options for entering into the risk arrangement—entering into either a value-based arrangement or a written contract for the VBE to assume risk from the payor.

Under the first option for risk arrangements, payors must be a VBE participant, which is permitted under our final definition of ''VBE participant.'' The payor (as a VBE participant) and the VBE can enter into a value-based arrangement for the VBE to assume substantial downside

financial risk. As we proposed and are finalizing in this rule, the introductory paragraph to 1001.952(ff) protects remuneration exchanged between a VBE and a VBE participant pursuant to a value-based arrangement. Therefore, remuneration exchanged pursuant to a payor's and a VBE's value-based arrangement could be protected by this safe harbor, including remuneration exchanged to implement a substantial downside financial risk methodology (*e.g.,* shared savings and losses), if the value-based arrangement meets all applicable conditions of the safe harbor. We do not believe this option would pose an unreasonable burden on the payor because a value-based arrangement requires only the provision of at least one value-based activity for a target patient population, and the payor and VBE already must enter into an agreement to effectuate the VBE's assumption of risk for the target patient population. We believe any burden would be outweighed by the benefits of safe harbor protection.

Under the second option, payors that do not wish to be part of the VBE may choose to enter into a written contract for purposes of the VBE assuming substantial downside financial risk. Under this option, payors would not be VBE participants, the written contract between the payor and the VBE would not be a value-based arrangement, and the payor would not be subject to the other conditions of the safe harbor. In such circumstances, these contracts must only meet the condition at paragraph 1001.952(ff)(2), *i.e.,* they must evidence the VBE's assumption of substantial downside financial risk from the payor. Remuneration exchanged pursuant to a risk assumption contract that is not a value-based arrangement is not protected by this safe harbor. The VBE and the payor would need to assess any potential remuneration exchanged pursuant to the risk arrangement contract and its compliance with the Federal anti-kickback statute.

In response to the commenter suggesting that providers should be permitted to assume risk without a payor, we recognize that there may be risk-based arrangements between and among providers that facilitate the goals set forth in the definition of ''value-based purpose'' and that seek to reduce overall costs. However, this safe harbor does not protect such arrangements. Other safe harbors may be available to protect such arrangements, such as the care coordination arrangements safe harbor or the personal services and management contracts and outcomes-based payment arrangements safe harbor.

Comment: Commenters requested that we clarify how the safe harbor would apply to arrangements involving certain categories of Federal health care program beneficiaries, such as Medicare fee-for-service patients or Indian Health Service (IHS) beneficiaries. In particular, multiple commenters expressed concern that, because Indian health care is compensated through IHS appropriations and the Medicare, Medicaid, and CHIP programs, Indian health care providers could not be risk-bearing entities, as required in the proposed substantial downside financial risk safe harbor.

Response: Given the requirement that the VBE assume substantial downside financial risk from a payor, this safe harbor will be available only for contracts or value-based arrangements where the target patient population is comprised of patients insured by a payor with which a VBE can enter into a risk arrangement. For example, whereas the safe harbor may be available for certain Medicaid direct contracting or managed care models,[52] it likely would not currently be available for an arrangement with a target patient population comprised of patients enrolled only in Medicare Parts A and B (*i.e.,* Medicare fee-for-service) because, outside of Innovation Center models and the Medicare Shared Savings Program, we are not aware of a mechanism that would allow a VBE to contract with the Medicare program to assume substantial downside financial risk for items and services for those patients.

It is also possible that Indian health care providers might not be risk-bearing entities for purposes of this safe harbor. This would not foreclose Indian health care providers from engaging in care coordination arrangements and seeking safe harbor protection under the care coordination arrangements safe harbor, which does not require the assumption of any risk (but is available for non-monetary remuneration in risk-bearing arrangements), or other available safe harbors, such as the personal services and management contracts and outcomes-based payments safe harbor that protects monetary payments for achieving quality outcomes. Moreover, the fact that an arrangement does not fit in a safe harbor does not make the arrangement unlawful, and the OIG advisory opinion process is also available for parties seeking a determination about a specific existing or proposed arrangement.

Comment: At least two commenters expressed support for the ability of a VBE participant to contract and assume risk on behalf of the VBE.

Response: We confirm that, for purposes of this final rule, parties have this flexibility. A VBE may assume risk from the payor directly or through a single VBE participant acting on its behalf because we recognize that not all VBEs may be a separate legal entity.

Comment: While acknowledging patients' right to choose a provider, a commenter requested that OIG not require parties to assume downside financial risk for those patients who choose to receive health care items or services from parties outside of the VBE. According to the commenter, physicians participating in VBEs that are clinically integrated need to refer patients within high-functioning networks that follow care management programs, and providers should not be required to assume downside financial risk for those patients who seek care outside the network.

Response: We are not adopting the commenter's suggestion to exclude those patients who choose to receive care outside a VBE from the calculation of downside financial risk. While we recognize that patients in the target patient population ultimately could select providers and suppliers both inside and outside the VBE, we believe the VBE and its VBE participants can still coordinate and manage the care of these patients and should be required to assume risk for these patients in order to benefit from the increased flexibility afforded by this safe harbor. In addition, allowing providers to remove patients from the calculation of downside risk if they choose any provider outside the VBE could lead to manipulation of the target patient population in ways that could compromise the quality of patient care, *e.g.,* providers might encourage more costly patients to obtain care elsewhere. This approach is consistent with the Medicare Shared Savings Program.

Comment: A medical device manufacturer asserted that this safe harbor should be expanded to recognize that, in many cases, the items or services for which the VBE is at risk will not necessarily be provided directly to patients in the target patient population but instead may be an ancillary part of their care under the value-based arrangement, such as products and services deployed by medical device manufacturers.

Response: We require that the VBE be at substantial downside financial risk

[52] *See* Center for Health Care Strategies, Inc., Value-Based Payments in Medicaid Managed Care: An Overview of State Approaches (Feb. 2016), *available at https://www.chcs.org/media/VBP-Brief_022216_FINAL.pdf.*

for providing or arranging for the provision of items and services for a target patient population and that the VBE participant assume a meaningful share of that risk. There is no requirement that such items and services be provided directly to the target patient population, and there is nothing in the safe harbor that prevents the VBE's risk from encompassing items and services for, but not provided directly to, the target patient population, such as ancillary products and services. However, pursuant to paragraph 1001.952(ff)(1)(v), manufacturers of devices or medical supplies are not eligible to use this safe harbor to exchange remuneration.

e. Phase-In Period

Summary of OIG Proposed Rule: To address start-up arrangements for parties preparing to take on risk, we proposed at paragraph 1001.952(ff)(1) that this safe harbor would protect remuneration exchanged between the VBE and a VBE participant during the 6 months prior to the date by which the VBE must assume substantial downside financial risk. We proposed that, during this phase-in period, the VBE must be contractually obligated to assume such risk from a payor.

Summary of Final Rule: We are finalizing the 6-month phase-in period, with modification, and relocating it to paragraph 1001.952(ff)(2).

Comment: Commenters overwhelmingly supported a phase-in period, noting that many providers and organizations will need time to assume downside financial risk. However, many commenters asserted that the proposed 6-month time period was insufficient and recommended a longer phase-in period, such as 1 or 2 years. These commenters expressed concern that, absent a longer phase-in period, the safe harbor would be available to only highly sophisticated and large organizations that already have the capacity to take on high levels of financial risk. Another commenter argued that a longer phase-in period is essential in order to allow newly formed or small VBEs the flexibility to establish baselines against which to measure losses or savings. Some commenters highlighted other justifications for a longer phase-in period, including the significant training and integration needed for the adoption of new software systems and the need for providers with less experience with value-based arrangements, including small or rural providers, to have more time to assume financial risk. Other commenters requested that OIG extend the phase-in period only in defined circumstances, *e.g.,* for VBEs created by independent medical practices or in circumstances where the 6-month phase-in period would place an undue burden on the parties to the arrangement. Finally, another commenter suggested a capacity-building period of 2 years where an entity would take on lower levels of downside financial risk and gradually build up to the thresholds set forth in the definition of ''substantial downside financial risk.''

Response: We solicited comments on whether 6 months was a sufficient timeframe for a phase-in period or whether a longer or shorter timeframe would be appropriate. Having reviewed the comments and considered the issue, we have determined that, while some parties interested in assuming substantial downside financial risk might benefit from a phase-in period of more than 6 months, a 6-month phase-in period, paired with the availability of the care coordination arrangements safe harbor, should provide a sufficient on-ramp for parties seeking safe harbor protection for start-up or capacity-building arrangements to prepare to assume substantial downside financial risk.

In addition, the changes we have made to the definition of ''substantial downside financial risk'' to replace the previous requirements for comparisons to historical benchmarks should allay concerns raised by newly formed or small entities about the time needed to establish baselines against which to measure losses or savings. In particular, the new standard for setting a benchmark provides flexibility to individuals and entities that may not have historical benchmarks to establish benchmarks using other appropriate data, such as regional or national data.

Comment: A commenter requested that OIG confirm that all remuneration exchanged during the phase-in period related to VBE participants' good faith efforts to set up the VBE or value-based arrangement would be protected, even if the value-based arrangement ultimately did not move forward.

Response: To qualify for protection during the phase-in period, the VBE must have a contract or a value-based arrangement with the payor to assume risk within the next 6 months. To illustrate, if a VBE enters into a contract with a payor on January 1, the VBE must assume substantial downside financial risk no later than July 1st. The phase-in period runs from January 1 to July 1 (or an earlier date if the VBE assumes risk sooner). We recognize that a VBE might discover during the phase-in period that it is unable to assume the planned risk because, for example, of a failure to achieve an adequate network or necessary infrastructure. Remuneration exchanged between a VBE and a VBE participant during the phase-in period would be protected even if the VBE ultimately does not assume substantial downside financial risk at the conclusion of the phase-in period, provided the VBE had entered into a contract or a value-based arrangement with the payor to assume substantial downside financial risk and all other safe harbor requirements were met.

With respect to the question about setting up a VBE, under the final rule, parties may not use the 6-month phase-in period to protect remuneration exchanged in order to set up a VBE because, as a condition of meeting the safe harbor, the VBE must already be in existence. In addition, there must be a value-based arrangement between the VBE and VBE participant that includes the exchange of payments or something of value for which safe harbor protection is sought. The remuneration under this value-based arrangement could relate to efforts to set up necessary infrastructure to assume risk for the target patient population.

Comment: A commenter asked OIG to protect all legitimate pre-arrangement activities associated with assuming risk, even where the VBE is not under a contractual obligation to assume risk. Another commenter asked whether payments by an academic medical center to physicians to maintain income levels during the phase-in period are protected.

Response: We decline to protect pre-arrangement activities when the VBE has not entered into a contract or a value-based arrangement to assume risk from a payor, although the actual assumption of risk need not occur for 6 months. The requirement that the VBE enter into a contract or value-based arrangement to assume risk is a critical safeguard to protect against parties' attempts to exploit the phase-in period of this safe harbor to protect problematic payments when they have no intention of entering into the risk arrangements required by the safe harbor.

Income guarantee payments would not satisfy any of the risk-based methodologies set forth in the definitions of ''substantial downside financial risk'' or ''meaningful share.'' Whether income guarantee payments to physicians could otherwise be protected by this safe harbor would depend on whether such remuneration satisfies all requirements of the safe harbor. For example, such payments likely would not satisfy the requirement that remuneration be directly connected to at least one of the three value-based

purposes defined in paragraph 1001.952(ee)(14)(x)(A)–(C). It seems unlikely that income guarantee payments would be directly connected to the deliberate organization of patient care activities and sharing of information to improve care for the target patient population, as the definition of coordination and management of care requires. Additionally, while we acknowledge that income guarantees could result in ancillary benefits to patients or could contribute to appropriate cost reductions, we consider it unlikely that income guarantee payments could be *directly* connected to improvements in the quality of care or appropriate reductions in costs.

f. Remuneration Used To Engage in Value-Based Activities

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ff)(3)(i) that the remuneration exchanged pursuant to this safe harbor must be used primarily to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk.

Summary of Final Rule: We are finalizing, with modifications, this requirement at paragraph 1001.952(ff)(4)(ii). First, for the reasons set forth in section III.B.3.e.ii of this preamble, we are replacing the word ''primarily'' with ''predominantly'' so that the safe harbor now requires the remuneration exchanged to be used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE has assumed (or has entered into a written contract or value-based arrangement to assume within the next 6 months) substantial downside financial risk. Second, we are modifying this requirement to provide that the remuneration exchanged pursuant to a methodology for the assumption of risk does not need to meet this condition if the remuneration is part of a value-based arrangement that meets all other safe harbor conditions. That is, remuneration exchanged between either a VBE and a payor (as a VBE participant) pursuant to a methodology that meets the definition of ''substantial downside financial risk,'' or between a VBE and a VBE participant (other than a payor) pursuant to a methodology that meets the definition of ''meaningful share,'' need not be used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk. Lastly, we are clarifying that the items and services to which the value-based activities must be directly connected are those for which the VBE has assumed (or has entered into a written contract or value-based arrangement to assume within the next 6 months) substantial downside financial risk. This clarification is in recognition that parties to a value-based arrangement may exchange remuneration during the phase-in period when the VBE has not yet assumed substantial downside financial risk but has entered into a written contract or value-based arrangement to assume such risk within the next 6 months.

Comment: Some commenters expressed general concern that this proposed requirement would be administratively burdensome, and at least one commenter more specifically stated that it would be burdensome to track how monetary remuneration is spent in order to ensure compliance with this requirement. Another commenter suggested that this requirement would preclude protection of remuneration in the form of shared savings. These commenters appeared to request that OIG remove this condition either in its entirety (thereby permitting parties to use any remuneration protected under this safe harbor for any purpose permissible under applicable law) or only with respect to monetary remuneration or a subset of monetary remuneration, such as shared savings and other performance-based payments. Alternatively, a commenter asserted that OIG should treat certain payments, such as bonus distributions and performance-based payments, as payments for the past performance of activities directly connected to the items and services for which the VBE is at risk.

Response: The commenters' concerns and recommendations appear to stem from a perceived difficulty with tracking and monitoring the VBE participant's use of the remuneration. In response to the commenter's concerns, we are revising this requirement to include the following modifier at the start of paragraph 1001.952(ff)(4)(i): Unless exchanged pursuant to risk methodologies defined in paragraph (9)(i) or (ii). With this modifier, monetary remuneration exchanged pursuant to a risk methodology that meets the definition of ''substantial downside financial risk'' or ''meaningful share,'' *i.e.,* the risk methodologies defined in paragraph 1001.952(ff)(9)(i) and (ii), does not need to be used predominantly to engage in value-based activities. Because such remuneration effectuates the assumption of risk required by the safe harbor, it is appropriate to exempt this remuneration from the requirement for remuneration to be used predominantly to engage in value-based activities.

All other remuneration exchanged must be used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE has assumed substantial downside financial risk. With respect to the commenters' concerns regarding tracking another party's use of such remuneration, we emphasize that the safe harbor does not require the offeror of remuneration to track the recipient's use to determine whether such use is consistent with the safe harbor requirement to predominantly use remuneration to engage in value-based activities for the target patient population. We recognize that all parties to the value-based arrangement would lose safe harbor protection if the recipient fails to satisfy the predominant use requirement, but we believe there are ways for an offeror to protect itself against this risk, such as by including terms in the signed writing requiring the recipient to use funds in a particular manner. With respect to a commenter's concern that this condition would preclude the protection of shared savings, this condition, as finalized, would not preclude the protection of shared savings, as long as the shared savings arrangement satisfies all of the safe harbor's conditions.

We are not persuaded by the suggestion that we allow remuneration to be used for any purpose permissible under applicable law. In order to use this safe harbor, the parties must have formed a value-based enterprise that has one or more value-based purposes. We believe that requiring remuneration to be used predominately for value-based activities associated with the target patient population is an important mechanism to help ensure that the parties are working toward these purposes.

Comment: Commenters stated that the requirement for parties to exchange remuneration that is used to engage in value-based activities that are ''directly connected'' to the items and services for which the VBE has assumed (or has entered into a contract to assume within the next 6 months) substantial downside financial risk could subject parties seeking protection under this safe harbor to undue scrutiny regarding what constitutes a direct connection.

Response: We believe parties are well-positioned to demonstrate that the value-based activities they undertake have a direct connection to the items and services provided to patients in the target patient population. Pursuant to paragraph 1001.952(ff)(5) of the safe

harbor, the value-based activities must be set forth in writing, which provides an opportunity for parties to document how such activities are directly connected to the items and services for which the VBE is at substantial downside financial risk.

By way of example, in a value-based arrangement where a VBE is at risk for an episode of care involving hospital and post-acute care, if the VBE furnishes or finances the provision of additional clinical staff or social workers for use by both a VBE participant hospital and a VBE participant skilled nursing facility, the clinical staff or social workers must predominantly engage in value-based activities that are directly connected to the items and services furnished during the episode of care for which the VBE is at substantial downside financial risk. In the OIG Proposed Rule, we provided an example involving a target patient population undergoing hip replacement surgery to show what it means to have a direct connection between the value-based activities and items and services for the target patient population. Using this same example under the final rule, if a VBE is at substantial downside financial risk for the items and services provided to patients in a target patient population undergoing hip replacement surgery, the VBE could give a VBE participant money to hire a staff member who predominately coordinates patients' transitions between care settings after hip replacement surgery. The VBE could not give the VBE participant money to hire a staff member who coordinates transitions between care settings for patients undergoing an array of surgical procedures other than hip replacement surgery.[53]

g. Direct Connection to Value-Based Purposes

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ff)(3)(ii) that the protected remuneration must be directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population.

Summary of Final Rule: We are finalizing, with modification, this condition at paragraph 1001.952(ff)(4)(i). The final rule provides that protected remuneration must be directly connected to at least one of the three value-based purposes defined in paragraph 1001.952(ee)(13)(x)(A)–(C). Remuneration may advance more than one value-based purpose.

We summarize and respond to comments specific to the substantial downside financial risk safe harbor regarding this condition below. For a more detailed discussion and a summary of the general comments received regarding the requirement for a direct connection to the coordination and management of care, as proposed in both the care coordination arrangements safe harbor and this safe harbor, and our responses, we refer readers to the care coordination arrangements safe harbor section discussion at section III.B.3.h.

Comment: A commenter asserted that all payment arrangements protected by this safe harbor should have as a value-based purpose a focus on cost reduction and quality improvement.

Response: In the context of remuneration exchanged pursuant to value-based arrangements where parties have met the requirements of the definitions of ''substantial downside financial risk'' and ''meaningful share,'' we recognize that it may be appropriate for parties to have value-based purposes related to achieving appropriate cost reductions or quality improvements. Accordingly, we are revising this condition to provide parties additional options for remuneration to be directly connected to at least one of three value-based purposes defined in paragraph 1001.952(ee)(13)(x)(A)–(C). Remuneration must be directly connected to one or more of the following value-based purposes: The coordination and management of care for the target patient population; improving the quality of care for the target patient population; and appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for the target patient population. Parties may choose to meet one or more of these three value-based purposes to satisfy this condition. For a more detailed discussion regarding these value-based purposes see section III.B.2.f.

h. Reductions in Medically Necessary Items or Services

Summary of OIG Proposed Rule: At proposed paragraph 1001.952(ff)(3)(iii), we proposed to require that the remuneration exchanged not induce the VBE participants to reduce or limit medically necessary items or services furnished to any patient.

Summary of Final Rule: We are finalizing, with modification, this condition at paragraph 1001.952(ff)(7)(iii). We are modifying the condition to clarify that the value-based arrangement (not merely the remuneration exchanged) may not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient. We summarize and respond to comments specific to the substantial downside financial risk safe harbor regarding this provision below. For a more detailed discussion and a summary of additional comments received regarding this requirement, as proposed in both the care coordination arrangements and substantial downside financial risk safe harbors, and our responses, we refer readers to the care coordination arrangements safe harbor discussion at section III.B.3.e.iii.

Comment: Multiple commenters supported additional conditions to safeguard against the risks of cherry-picking, lemon-dropping, and stinting on care. For example, a commenter stated that the assumption of downside financial risk presented a heightened risk for cherry-picking patients, discharging highly complex, rare, or costly patients, and stinting on care for patients with high medical needs. The commenter appeared to recommend Federal Government oversight of value-based arrangements to address these risks. Another commenter recommended OIG formally monitor for cherry-picking or lemon-dropping activities and eliminate eligibility for safe harbor protection for parties inappropriately engaged in these activities.

Response: We acknowledge that assuming downside financial risk may heighten the risks identified by the commenter. We believe that the parameters created by the value-based definitions as well as the safeguards in this safe harbor protect against such conduct. For example, the definition of ''target patient population'' requires that the VBE or its VBE participants identify the target patient population using legitimate criteria, and criteria that seek to exclude costly or noncompliant patients would not be legitimate. However, in response to the comment that the nature of value-based arrangements, themselves, can create incentives for stinting or cherry-picking, we are expanding this prohibition to apply to not only the remuneration exchanged between the parties but also all terms and conditions of a value-based arrangement.

With respect to OIG's oversight, we anticipate that individuals and entities that are part of a value-based enterprise will be subject to OIG's program integrity and oversight activities to the same extent as other individuals and entities that engage in Federal health care program business.

[53] 84 FR 55694, 55718 (Oct. 17, 2019).

i. Ownership or Investment Interests

Summary of OIG Proposed Rule: At proposed paragraph 1001.952(ff)(3)(iv), we proposed that this safe harbor would not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest.

Summary of Final Rule: We are finalizing, without modification, this condition and relocating it to paragraph 1001.952(ff)(4)(iii).

Comment: A few commenters opposed this condition. For example, a commenter asserted that some potential participants may not be comfortable investing in a VBE where such investment is unprotected by safe harbors and therefore may avoid involvement in otherwise beneficial substantial downside financial risk arrangements. Another commenter urged OIG to clarify that it was not our intent to prohibit VBE participants from establishing a corporate structure for a VBE in which the participants may receive an equity interest, stating that, without such a clarification, the safe harbor would unnecessarily restrict the ability of individuals and entities to dictate the corporate structure of VBEs they create.

Response: We do not view protection for ownership or investment interests as fundamental to removing barriers to parties entering into value-based arrangements and are not protecting them under this safe harbor. Parties seeking to protect a particular ownership or investment interest may look to other safe harbors (*e.g.,* the safe harbor for investment interests, paragraph 1001.952(a), which protects certain investment interests if all requirements of the safe harbor are met), and the advisory opinion process remains available.

j. Remuneration From Individuals or Entities Outside the Applicable VBE

Summary of OIG Proposed Rule: At proposed paragraph 1001.952(ff)(3)(v), we proposed that the safe harbor would not protect remuneration funded, or otherwise resulting from contributions, by an individual or entity outside of the applicable VBE.

Summary of Final Rule: We are not finalizing this condition.

Comment: A commenter asserted that imposing this requirement would inhibit contributions or funding by an affiliate of a VBE or a VBE participant (*e.g.,* a parent organization). Another commenter suggested OIG permit ''outside'' donations under the substantial downside financial risk safe harbor when the donation would benefit a VBE's patients and the third-party donor would have no direction or control over how the funds would be spent.

Response: We are not finalizing this condition because of concerns that it may be unduly prescriptive and for the reasons described at section III.3.e.iv related to the similar proposal for the care coordination arrangements safe harbor. However, the exchange of remuneration between parties other than the VBE and a VBE participant (*e.g.,* remuneration exchanged between a third-party donor and a VBE participant or a VBE) would not be protected by this or any value-based safe harbor. Similarly, in the circumstances presented by the commenter, we would not view contributions or funding from an affiliate of a VBE (that is not a VBE participant) to that VBE as qualifying for protection under this or any value-based safe harbor. However, under this final rule, the mere fact that an affiliate of a VBE exchanges remuneration with that VBE would not preclude safe harbor protection for value-based arrangements between that VBE and its VBE participants.

Comment: A commenter requested that we address how the exclusion of safe harbor protection for remuneration funded, or otherwise resulting from contributions, by an individual or entity outside of the applicable VBE would operate where a VBE sought to enter into a value-based arrangement with a payor that was not, itself, a VBE participant.

Response: As noted above, we are not finalizing the proposed condition. For purposes of the value-based safe harbors, we are finalizing a definition of ''value-based arrangement'' in paragraph 1001.952(ee)(14)(vii) that requires the arrangement to be only between or among the VBE and one or more of its VBE participants or between or among VBE participants in the same VBE.

However, the modification explained in section III.B.4.d above, addresses the commenter's concern regarding assuming risk from a payor that is not a VBE participant. In that section, we explained that, while a payor could opt to be a VBE participant, it need not do so in order for a VBE to contract to assume substantial downside financial risk from a payor. However, unless the payor is a VBE participant, this safe harbor would not protect the remuneration exchanged between the payor and the VBE.

k. Writing

Summary of OIG Proposed Rule: At proposed paragraph 1001.952(ff)(4), we proposed that the terms of the value-based arrangement must be set forth in a signed writing that contains, among other information, a description of the nature and extent of the VBE's substantial downside financial risk for the target patient population and a description of the manner in which the recipient meaningfully shares in the VBE's substantial downside financial risk.

Summary of Final Rule: We are finalizing, with modifications, this condition at paragraph 1001.952(ff)(5). The modifications are based on public comments. First, parties must document the manner in which the VBE assumes risk from a payor and the VBE participant assumes a meaningful share of such risk. Second, the writing requirement can be satisfied by a collection of documents. Third, we are not requiring documentation of the offeror's costs. Fourth, the writing must be established in advance of, or contemporaneous with, the commencement of the value-based arrangement ''*and* any material change,'' instead of ''*or* any material change.'' Thus, the initial terms of the value-based arrangement must be set forth in the signed writing, in advance of, or contemporaneous with the commencement of the arrangement, and any material change to the value-based arrangement also must be set forth in the signed writing in advance of, or contemporaneous with the commencement of the material change. As with the similar modification we are making to the writing requirement in the care coordination arrangements safe harbor, these are the logical junctures where the writing requirement particularly serves its transparency purposes. Our proposed regulatory text did not make clear that the writing was needed at both junctures; our modifications more clearly express that policy.

This writing requirement does not apply to the contracts between a payor and a VBE in circumstances where the payor is not a VBE participant. Such contracts would not constitute value-based arrangements, subject to this condition. However, as set forth in paragraph 1001.952(ff)(2), such contracts must be in writing.

For further discussion of the general comments we received regarding a writing requirement in the value-based safe harbors, we refer readers to section III.B.3.d discussing the writing requirement for purposes of the care coordination arrangements safe harbor; in this section, we respond only to the comments specific to the proposed substantial downside financial risk safe harbor's writing requirement.

Comment: A commenter recommended that OIG revise this condition of the substantial downside financial risk safe harbor to remove the requirement that parties specify the type and the offeror's cost of the remuneration. The commenter stated that the offeror's cost is not material to the arrangement because the safe harbor does not include a contribution requirement and, furthermore, may be difficult to determine.

Response: We agree and are removing the requirement that the parties include the offeror's costs in the writing.

l. Does Not Take Into Account the Volume or Value of, or Condition Remuneration on, Business or Patients Not Covered Under the Value-Based Arrangement

Summary of OIG Proposed Rule: At proposed paragraph 1001.952(ff)(5), we proposed that the VBE or VBE participant offering the remuneration could not take into account the volume or value of, or condition the remuneration on, referrals of patients outside of the target patient population or business not covered under the value-based arrangement. This safeguard is identical to that proposed for the care coordination arrangements safe harbor.

Summary of Final Rule: We are finalizing this condition, without modification and relocating it to paragraph 1001.952(ff)(6). For a more detailed discussion and a summary of our responses to the comments received on this condition and our rationale for finalizing it, we refer readers to the care coordination arrangements safe harbor discussion at III.B.3.f. Comments received on this topic addressed the condition as it applied to the value-based safe harbors generally; we did not receive separate comments on this condition specific to this safe harbor.

m. Preserving Clinical Decision-Making

Summary of OIG Proposed Rule: At proposed paragraph 1001.952(ff)(6)(i), we proposed that value-based arrangements must not limit VBE participants' ability to make decisions in the best interests of their patients. In addition, at proposed paragraph 1001.952(ff)(6)(ii) we proposed that value-based arrangements cannot direct or restrict referrals to a particular provider, practitioner, or supplier if: (i) A patient expresses a preference for a different practitioner, provider, or supplier; (ii) the patient's payor determines the provider, practitioner, or supplier; or (iii) such direction or restriction is contrary to applicable law or regulations under titles XVIII and XIX of the Act. We proposed to interpret this condition consistent with the parallel condition proposed for the care coordination arrangements safe harbor.

Summary of Final Rule: We are finalizing, with modification, the proposed condition that the value-based arrangement must not limit the VBE participant's ability to make decisions in the best interests of its patients at paragraph 1001.952(ff)(7)(i). We are making a technical correction to change ''their patients'' to ''its patients.'' We also are finalizing, with modification, the condition related to directing or restricting referrals, at paragraph 1001.952(ff)(7)(ii). We are deleting ''or regulations'' from the proposed provision because regulations are captured by the term ''applicable law.''

For a more detailed discussion, summaries of comments we received regarding this requirement, as proposed in each of the value-based safe harbors, and our responses, we refer readers to the discussion of this condition in the care coordination arrangements safe harbor at section III.B.3. Below we discuss the comments we received on this condition specific to the proposed substantial downside financial risk safe harbor.

Comment: A commenter requested that OIG clarify how this requirement would apply to an arrangement involving patients who are covered by managed care payors, where patient preferences are likely to be limited.

Response: If a managed care payor determines the providers, practitioners, or suppliers from whom patients may seek health care items and services under a managed care plan, then the value-based arrangement could not direct or restrict referrals to a particular provider, practitioner, or supplier in a contrary manner.

n. Materials and Records

Summary of OIG Proposed Rule: At proposed paragraph 1001.952(ff)(7), we proposed to require that the VBE or its VBE participants make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of the safe harbor. We solicited comments regarding whether we should require parties to maintain materials and records for a set period of time (*e.g.,* at least 6 years or 10 years).

Summary of Final Rule: We are finalizing, with modification, the materials and records requirement. We are specifying that, for a period of at least 6 years, the VBE or its VBE participants must maintain records and materials sufficient to establish compliance with the conditions of the safe harbor.

This requirement will promote transparency and facilitate alignment with CMS's parallel value-based exception. For a more detailed discussion and a summary of and responses to the comments received about the records requirement, as proposed in each of the value-based safe harbors, we refer readers to the discussion of this condition in the care coordination arrangements safe harbor at section III.B.3.n. Comments received on this topic addressed the requirement as it applied to the value-based safe harbors generally; we did not receive separate comments on this requirement specific to this safe harbor.

o. Marketing of Items or Services or Patient Recruitment Activities

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(ff)(6)(iii) a condition to bar protection for remuneration exchanged pursuant to value-based arrangements that include marketing to patients of items or services or engaging in patient recruitment activities. We proposed to interpret this condition consistent with our interpretation of the same proposed requirement in the care coordination arrangements safe harbor.

Summary of Final Rule: We are finalizing this requirement, with modifications and relocating it to paragraph 1001.952(ff)(4)(v). As with the care coordination arrangements safe harbor, rather than prohibiting all marketing and patient recruitment activities, we are modifying this provision to prohibit the exchange of remuneration for the purpose of marketing items or services furnished by the VBE or VBE participants to patients or for the purpose of patient recruitment activities. Comments received on this topic addressed the requirement as it applied to the value-based safe harbors generally; we did not receive separate comments on this requirement specific to this safe harbor. Consequently, we refer readers to the discussion in section III.B.3.j of this condition in the care coordination arrangements safe harbor for a summary of applicable comments, our responses, and a more detailed discussion of this standard, including our rationale for the modification being made.

p. Downstream Arrangements

Summary of OIG Proposed Rule: We proposed to protect only remuneration exchanged between a VBE and a VBE participant at paragraph 1001.952(ff).

Summary of Final Rule: We are finalizing, without modification, the requirement that the exchange of remuneration be between the VBE and

a VBE participant in the introductory paragraph of 1001.952(ff).

Comment: A commenter agreed with our proposal to limit this safe harbor to remuneration exchanged solely between the VBE and a VBE participant and acknowledged the potential fraud and abuse risks inherent in downstream arrangements where a contracting party has assumed little or no financial risk. However, the majority of commenters advocated for extending safe harbor protection to remuneration that passes between and among VBE participants, or between VBE participants and downstream contractors. A commenter stated that downstream arrangements are essential to facilitating care coordination efforts, while another commenter asserted that requiring a VBE participant to meaningfully share in the VBE's substantial downside financial risk appropriately curtails any fee-for-service incentives. A commenter posited that this requirement would result in value-based activities being inefficiently routed through the VBE, and another commenter questioned why this safe harbor only protects remuneration between a VBE and VBE participant when the care coordination arrangements safe harbor more broadly protects remuneration between a VBE and a VBE participant or between VBE participants.

Response: We did not propose to protect arrangements where remuneration is passed from one VBE participant to another VBE participant or from a VBE participant to a downstream contractor. In this final rule, we are limiting safe harbor protection to the exchange of remuneration between the VBE and a VBE participant for which the combination of safe harbor conditions was designed. This safe harbor provides greater regulatory flexibility than the care coordination arrangements safe harbor, and as a result, we decline to extend safe harbor protection to downstream financial arrangements to which the VBE is not a party and that may not include all of the safeguards required by this safe harbor, including requirements related to the assumption of downside financial risk. A VBE participant seeking to exchange remuneration with another VBE participant may look to the care coordination arrangements safe harbor or other safe harbors, such as the personal services and management contracts and outcomes-based payments safe harbor.

Comment: A commenter expressed concern that limiting safe harbor protection to remuneration exchanged between the VBE and a VBE participant would be unworkable if the applicable VBE were comprised of an informal network of individuals and entities (versus a separate legal entity). In particular, the commenter seemed to believe that, in such circumstances, the VBE participants would not be able to protect any remuneration using this safe harbor.

Response: This safe harbor requires that a VBE assume substantial downside financial risk for certain items and services provided to the target patient population. In circumstances where the VBE is not a formal legal entity, but rather is comprised of a network of VBE participants, a single VBE participant may act on behalf of the VBE to contract or enter into a value-based arrangement with a payor to assume substantial downside financial risk. In such circumstances, this safe harbor could protect the exchange of remuneration between the VBE participant acting on behalf of the VBE and other VBE participants. We note that, while different VBE participants may act on behalf of the VBE at different times during the term of the value-based arrangement, only remuneration between a VBE participant acting on behalf of the VBE and another VBE participant may be protected. The safe harbor would not protect remuneration exchanged between two VBE participants, neither of whom are currently acting on behalf of the VBE.

q. Possible Additional Safeguards

Summary of OIG Proposed Rule: We stated in the preamble to the OIG Proposed Rule that we were considering adopting specified additional safeguards in the final rule, including a commercial reasonableness requirement, a monitoring standard, a cost-shifting prohibition, and a requirement to submit information to the Department regarding the VBE, the VBE participants, and the value-based arrangement.

Summary of Final Rule: We are not finalizing these proposed conditions. Upon further consideration, we do not consider them necessary to mitigate fraud and abuse risk given the overall structure and totality of conditions in the final safe harbor.

Comment: We received a variety of comments regarding potential additional safeguards in the substantial downside financial risk safe harbor. A commenter opposed the addition of a commercial reasonableness requirement, asserting that it would be inconsistent with CMS's similar exception and potentially would chill innovation where parties have assumed downside risk. Several commenters suggested including additional transparency requirements for patients. A commenter recommended that we include a prohibition on inappropriate cost shifting to Federal health care programs. A few commenters suggested that OIG require objective and quantifiable outcome measures to show the remuneration exchanged enhances patient outcomes. Another commenter urged us to include a termination provision similar to that in the care coordination arrangements safe harbor.

Response: We are not imposing a commercial reasonableness requirement in this safe harbor in recognition of the VBE and its VBE participants assuming substantial downside financial risk. We believe the assumption of downside financial risk helps to ensure that the remuneration is exchanged in order to achieve value-based purposes rather than to pay for referrals, which is at the core of the commercial reasonableness standard in other safe harbors. We did not propose patient transparency or notice requirements and are not including such conditions in this final rule. While parties may choose to provide patient notifications, such a condition in the safe harbor would not add appreciable additional protection against payments for referrals. We also are not including a cost-shifting prohibition, in recognition that the assumption of substantial downside financial risk is intended to drive a reduction in costs, which may include Federal health care program costs.

While parties may include termination provisions or outcome measure requirements as part of their value-based arrangements, we are not requiring these terms as a condition of the safe harbor.

5. Value-Based Arrangements With Full Financial Risk (42 CFR 1001.952(gg))

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg) a full financial risk safe harbor that would protect remuneration exchanged between a VBE and a VBE participant pursuant to a value-based arrangement where the VBE has assumed, or is contractually obligated to assume within the next 6 months, full financial risk, as set out at proposed paragraph 1001.952(gg)(1). We proposed to define ''full financial risk'' at proposed paragraph 1001.952(9)(i) to mean that ''the VBE is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the applicable payor.''

We proposed that the full financial risk safe harbor would include certain safeguards, such as requirements that:

(i) The VBE have a signed writing with the payor that specifies the target patient population and terms evidencing full financial risk (proposed paragraph 1001.952(gg)(1)); (ii) the parties have a signed writing that specifies the material terms of the value-based arrangement (proposed paragraph 1001.952(gg)(2)); and (iii) the VBE participant not claim payment from a payor (proposed paragraph 1001.952(gg)(3)). Further, we proposed at paragraph 1001.952(gg)(4) that the remuneration exchanged be used primarily to engage in value-based activities; be directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population; not induce reductions or limitations of medically necessary care; and not be funded by outside contributions. At proposed paragraph 1001.952(gg)(5), we proposed a restriction on taking into account the volume or value of business outside the value-based arrangement, and at proposed paragraph 1001.952(gg)(6), we proposed that the VBE provide or arrange for an operational utilization review program and quality assurance program. At proposed paragraph 1001.952(gg)(7), we proposed a restriction on marketing and patient recruitment, and at proposed paragraph 1001.952(gg)(8), we proposed a requirement to make available materials and records to the Secretary.

Summary of Final Rule: We are finalizing, with modifications, the safe harbor at paragraph 1001.952(gg). We are modifying the definition of ''full financial risk'' at paragraph 1001.952(gg)(10)(ii) to require the VBE to be at risk on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year. We are defining ''prospective basis'' at paragraph 1001.952(gg)(10)(ii) to mean the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to the provision of items and services to patients in the target patient population.

We are finalizing the proposed safeguards, with some modifications at paragraphs 1001.952(gg)(2)–(8), as explained in more detail in the topical discussions below. In addition, we have added a list of entities ineligible to use the safe harbor at paragraph 1001.952(gg)(1) for the reasons set forth in the discussion of the definition of ''VBE participant'' at section III.B.2.e.

a. General Comments

Comment: While some commenters expressed support for this proposed safe harbor, multiple commenters conveyed their concerns that this safe harbor may have limited application. For example, some commenters noted that the proposed safe harbor requirements, including the definition of ''full financial risk,'' would limit the safe harbor to only large integrated delivery systems capable of providing nearly all Medicare and Medicaid covered services to a target patient population and would disadvantage small and rural practices and practices serving underserved areas. Other commenters highlighted a potential intersection between certain state insurance and licensure laws and the proposed safe harbor requirements that could, according to the commenters, limit the availability of safe harbor protection only to those entities that could comply with such state laws, some of which may require a VBE to be licensed as a health care services plan. To address this issue, a commenter requested revisions to the proposed safe harbor to make safe harbor protection available to advanced, risk-bearing provider networks in states with such licensure requirements.

Response: We designed this safe harbor to provide significant flexibility under the Federal anti-kickback statute in light of the level of financial risk assumed by the parties. We crafted the ''full financial risk'' definition, as well as the conditions of this safe harbor, to balance the additional flexibilities under the anti-kickback statute with appropriate safeguards against both risks associated with fee-for-service payment systems, such as overutilization and skewed decision-making, and risks present in risk-based arrangements, including stinting on care (underutilization), cherry-picking lucrative or adherent patients, and lemon-dropping costly or noncompliant patients. We believe that the definition of ''full financial risk,'' combined with the conditions of this safe harbor, appropriately balance the flexibilities afforded by this safe harbor with any identified program integrity risks.

We understand that there currently are a limited number of providers assuming the level of risk required by this safe harbor. The purpose of implementing a full financial risk safe harbor is to remove one potential barrier to providers taking on more risk and having additional financial incentives to coordinate care. Providers assessing whether they can move to full financial risk in the future can consider this safe harbor and the flexibilities it offers under the Federal anti-kickback statute as one factor in that determination. There are other factors that parties would consider in the decision to assume a higher level of risk, including some considerations raised by the commenters. While safe harbors cannot address all factors that may prohibit a provider from taking on full financial risk, this safe harbor is designed to encourage more providers to do so. We also note that this safe harbor conditions protection on the VBE assuming full financial risk from the payor for the items and services. It does not require the VBE to assume other functions from the payor, such as enrollment, grievance and appeals, solvency standards, and other administrative functions performed by payors.

We recognize that some states may have laws that limit providers and other health care entities from taking on full financial risk unless they form licensed health care plans or meet other licensure requirements. We have attempted to create significant flexibility under the Federal anti-kickback statute while recognizing that parties still must comply with applicable state laws. For example, this safe harbor provides flexibility around how the VBE assumes full financial risk from a payor. Such flexibilities provide payors, VBEs, and VBE participants with options to structure arrangements that are consistent with the safe harbor and state laws. Nothing in these safe harbors preempts any applicable state law (unless such state law incorporates the Federal law by reference). Other safe harbors may be available to parties unable—by virtue of any state law requirements—to structure an arrangement that satisfies the conditions of this safe harbor.

Comment: A commenter suggested that we consider a new safe harbor or a fraud and abuse waiver for Medicare Advantage plans testing value-based arrangements. The commenter asserted that such a safe harbor or waiver would allow entities not otherwise eligible for protection under the value-based safe harbors to participate in value-based arrangements.

Response: We did not propose a safe harbor or a fraud and abuse waiver specific to Medicare Advantage plans, and thus we are not finalizing such safe harbor or waiver in this final rule. This safe harbor may be available to protect remuneration exchanged under certain Medicare Advantage plan arrangements, provided the plan enters into a contract or a value-based arrangement with a VBE pursuant to which the VBE assumes full financial risk from the

plan. We also note that there may be other existing safe harbors not modified by this final rule that are available to protect financial arrangements involving a Medicare Advantage plan, such as paragraphs 1001.952(t) and (u), and the advisory opinion process remains available.

Comment: While a commenter expressed support for OIG's and CMS's consistent definitions of full financial risk, others requested that OIG finalize a full financial risk safe harbor that further aligns with CMS's parallel full risk exception. These commenters generally urged OIG and CMS to impose the same risk thresholds and requirements for purposes of the full financial risk safe harbor and the CMS full risk exception.

Response: As with the OIG Proposed Rule, in this final rule, we have endeavored to align our full financial risk safe harbor to the greatest extent possible with CMS's full risk exception. The definition of ''full financial risk'' we are finalizing is more closely aligned with the definition of ''full financial risk'' that CMS is finalizing in its full risk exception. However, reflecting statutory differences that exist between the Federal anti-kickback statute and the physician self-referral law, explained further in section III.A.1, the full financial risk safe harbor differs from CMS's full risk exception. For example, in recognition of the statutory differences between the two laws, the safe harbor includes conditions that differ from those in CMS's parallel exception, such as the requirement that the value-based arrangement be set forth in writing and that the VBE provide or arrange for a quality assurance program for services furnished to the target patient population.

b. Definitions

i. Full Financial Risk

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(9)(i) that a VBE would be at ''full financial risk'' for the cost of care of a target patient population if the VBE is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the applicable payor.

Summary of Final Rule: We are finalizing, with modifications, a definition of ''full financial risk'' at paragraph 1001.952(gg)(9)(i). The modifications, based on public comments, provide parties with additional flexibility in the manner in which the VBE assumes risk from the applicable payor. The definition of ''full financial risk'' now requires the VBE to be at risk on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year. ''Prospective basis,'' as defined at paragraph 1001.952(gg)(9)(ii), means the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to the provision of items and services to patients in the target patient population.

Comment: While at least one commenter supported the definition of ''full financial risk,'' as proposed, the vast majority of commenters recommended that we revise the definition to encompass arrangements where the VBE assumes risk for less than all of the items and services covered by the applicable payor. For example, many commenters recommended that the VBE be required to have risk only for ''substantially all'' items and services furnished to the target patient population, which commenters suggested could be defined as 75 percent of such items and services. Other commenters requested that full financial risk include assuming risk for a much more specifically defined set of services (*e.g.,* hospital inpatient and outpatient care or ongoing services related to breast care). Other commenters asked OIG to carve out certain high-cost or specialty items and services (*e.g.,* organ transplants or pharmacy benefits) or new technologies that were not incorporated into rate calculations from the scope of items and services for which a VBE must be at risk.

Some commenters requested that the definition of ''full financial risk'' include risk only for all of the items and services required to treat a particular disease or condition or an episode of care (*e.g.,* risk for all of the items and services required to treat diabetes for patients with diabetes in the target patient population or an episode of care for a knee replacement). Another commenter asked OIG to permit partial capitation arrangements and, lastly some commenters contended that full financial risk should include risk for only the items and services to which the remuneration relates. Many of these commenters asserted that VBE participants would still be incentivized to maximize quality and efficiency of care even where the VBE assumes risk for less than all items and services provided to the target patient population by the applicable payor.

Response: We are finalizing a definition of ''full financial risk'' that requires the VBE to be at risk on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year. We decline to extend safe harbor protection under this safe harbor where a VBE has assumed risk for only a subset of items and services, such as for 75 percent of items and services, for all items and services except certain high-cost or specialty items and services, or for only the items and services to which the remuneration relates, although we note that the substantial downside financial risk safe harbor may be available for such arrangements. Additionally, a VBE could assume full financial risk for patients with a particular disease condition (*e.g.,* patients with diabetes) by selecting a target patient population comprised only of patients with diabetes, but the VBE must cover all items and services for those patients. Therefore, while a VBE must be at risk for all items and services furnished to the target patient population, the VBE can limit the number of patients for whom it assumes full financial risk through its selection of the target patient population, as long as the VBE selects the target patient population using legitimate and verifiable criteria, among other requirements.

In light of the significant flexibility we are offering under this safe harbor, we believe the risk level we are requiring for VBEs is necessary to reduce traditional fraud and abuse concerns associated with payment systems that incorporate, in whole or in part, fee-for-service reimbursement methodologies. While we appreciate the challenges associated with assuming risk for certain high-cost or specialty items and services or new technologies, VBEs may address such challenges through arrangements to protect against catastrophic losses, such as risk-adjustment or reinsurance agreements, without losing safe harbor protection.

Comment: Some commenters asked OIG to clarify whether the VBE and its VBE participants can collectively be at risk for items and services to the target patient population, such as by each VBE participant being at risk only for the services it provides.

Response: A value-based enterprise is a collection of two or more VBE participants. As such, some or all of the VBE participants that comprise the VBE can combine their respective risk to satisfy the definition of ''full financial risk'' as long as the VBE participants' collective risk amounts to risk for all items and services covered by the

applicable payor for the target patient population.

Comment: A physicians' trade organization expressed concern that smaller practices that attempt to assume too much risk could result in the closures of community practices and consolidation. Another commenter highlighted that there may be substantial up-front investments that can strain any physician practice's limited resources but can be particularly challenging for small, rural, or underserved practices with smaller patient pools to spread risk.

Response: We recognize that the full financial risk safe harbor requires a level of risk that many in the health care industry may not currently be able to assume. For parties seeking protection for remuneration exchanged pursuant to risk arrangements requiring a lower level of risk, the substantial downside financial risk safe harbor or the care coordination arrangements safe harbor may be available. This safe harbor does not require small, rural, or community practices or practices serving underserved populations to assume full financial risk or make substantial up-front investments on their own. Parties have flexibility in establishing a VBE, which must have at least two VBE participants but can have any number of additional VBE participants. We believe the ''VBE participant'' definition and the safe harbors in this final rule provide small, rural, and community practices and practices serving underserved populations options to enter into arrangements to assume higher levels of risk without having to integrate practices or become part of a larger health care system.

Further, we believe that establishing a VBE with other providers, either similarly situated entities or larger entities, could help practices (including small, rural, and community practices) take on more risk and mitigate potential financial shocks. As value-based arrangements continue to proliferate, we believe there may be opportunities for these types of practices to form VBEs, take on risk, and potentially have success in reducing costs and coordinating care.

Comment: Commenters requested that the definition of ''full financial risk'' expressly include payments based on global budgets, as well as capitation and other alternative payment methodologies.

Response: While the definition of ''full financial risk'' does not expressly list global budget or capitation payment methodologies as permissible payment methodologies, we confirm that such prospective payment methodologies would satisfy the definition of ''full financial risk'' as long as the global budget or capitation payments covered the cost of all items and services covered by the applicable payor for the target patient population for a term of at least 1 year. Without additional detail related to the alternative payment methodologies referenced by the commenter, we are unable to opine on whether such payment methodologies would meet the definition of ''full financial risk.'' Parties also may request an advisory opinion from OIG to determine whether an arrangement meets the definition of ''full financial risk'' and the conditions of the full financial risk safe harbor or is otherwise sufficiently low risk under the Federal anti-kickback statute to receive prospective immunity from administrative sanctions by OIG.

Comment: A commenter requested that OIG explain why the proposed definition of ''full financial risk'' required that the payor prospectively pay the VBE.

Response: We proposed a definition of ''full financial risk'' that required prospective payment, and we stated in the OIG Proposed Rule that we interpreted ''prospective'' to mean the anticipated cost of all items and services covered by the applicable payor for the target patient population had been both determined and paid in advance (as opposed to billing under the otherwise applicable payment systems and undergoing a retrospective reconciliation after items and services have been furnished). In this final rule, we are revising the definition of full financial risk to require risk on a prospective basis and defining ''prospective basis'' to mean the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to the provision of items and services to patients in the target patient population. As such, the VBE no longer needs to be prospectively paid by the applicable payor prior to the provision of items and services to each patient in the target patient population. Instead, the VBE must simply assume financial responsibility prior to the provision of items and services.

We are requiring the assumption of risk on a prospective basis not only in recognition of the additional flexibilities under the Federal anti-kickback statute that this safe harbor affords but also because risk assumption can serve to limit the potential harms that may result from financial incentives inherent to fee-for-service payments systems, such as overutilization and skewed medical decision-making. For example, if providers know the amount of reimbursement they will receive for providing items and services to the target patient population before providing such items and services, then the providers may be less likely to order excessive tests or otherwise provide unnecessary items and services to the patients.[54]

Comment: We received various comments regarding how a payor could transfer risk to the VBE. For example, a commenter requested confirmation that the payor and VBE could engage in retrospective reconciliations. Another commenter asserted that OIG should add language to the safe harbor stating that risk, both at the enterprise level and at the VBE participant level, can be through front-end withholds or dues assessments and need not be through a back-end repayment. A commenter further asked whether, as long as the payment covers a particular period, the payor could pay the VBE at the end or in the middle of the coverage period.

Response: Under the revised definition of ''full financial risk,'' a payor could pay the VBE at any point in the coverage period and engage in retrospective reconciliations, as long as the VBE has assumed full financial risk for a term of at least 1 year prior to the provision of items and services to patients in the target patient population. We also are not dictating the manner in which the VBE exchanges remuneration with VBE participants, so a VBE could impose front-end withholds or dues assessments on VBE participants.

Comment: A commenter asserted that the OIG Proposed Rule's proposed definition of ''full financial risk'' allowed a payor to make payments to physician practices to offset losses that the practices incurred.

Response: This safe harbor would not protect payments from a payor to a physician practice that is a VBE participant to offset losses the practice incurred because the safe harbor prohibits a VBE participant from claiming payment in any form from a payor for the items and services covered under the value-based arrangement. In other words, under the terms of this safe harbor, the VBE must assume full financial risk for the cost of all items

[54] Mark W. Friedberg, Peggy C. Chen, Chapin White et al., *Effects of Health Care Payment Models on Physician Practice in the United States,* RAND Corporation (2015); K. John McConnell, Stephanie Renfro, Richard C. Lindrooth et al., *Oregon's Medicaid Reform And Transition To Global Budgets Were Associated With Reductions In Expenditures,* Health Affairs (Mar. 2017); James C. Robinson, Stephen M. Shortnell et al., *Quality-Based Payment for Medical Groups and Individual Physicians, INQUIRY: The Journal of Health Care Organization, Provision, and Financing* (May 2009).

and services covered by the applicable payor; this means that any claims submitted to a payor by a VBE participant related to such items and services—including a claim for payment to offset losses incurred—would fail this requirement. The VBE, however, may enter into reinsurance or other risk-adjustment arrangements and could address losses incurred by VBE participants by using reinsurance payments, for example, to reimburse VBE participants for such losses.

Comment: Many commenters appreciated OIG's position that the definition of ''full financial risk'' would not prohibit a VBE from entering into arrangements to protect against catastrophic losses. Multiple commenters requested guidance on the risk mitigation terms that full-risk arrangements can include while satisfying the requirements of the safe harbor, including whether there is a particular threshold on the amount of loss coverage. A commenter specifically asked whether incentive arrangements requiring stop-loss protection to meet existing physician incentive regulations in Federal health care programs would qualify as protecting against catastrophic losses under the full financial risk safe harbor.

Response: We are not imposing a specific limit on the amount of loss coverage a VBE may have, but as we stated in the OIG Proposed Rule, we would expect any stop-loss or other risk adjustment arrangements to act as protection for the VBE against catastrophic losses and not as a means to shift material financial risk back to the payor. Whether stop-loss protection required by the existing physician incentive regulations would be appropriate stop-loss protection for a VBE assuming risk pursuant to this safe harbor may depend on a number of factors, including the structure of the VBE, scope of the target patient population, and items and services covered by the applicable payor.

Comment: A commenter expressed concern that, because the proposed definition of ''full financial risk'' requires the assumption of risk for the cost of all items and services covered by the applicable payor, it would by default necessitate the involvement of hospitals as VBE participants. The commenter appeared to believe that this would lead to further consolidation of the health care industry.

Response: It is not the intent of this rule to foster industry consolidation. Rather, this rule aims to increase options for parties to create a range of innovative arrangements eligible for safe harbor protection. The safe harbor does not require all parties providing items and services to the target patient population to be VBE participants and thus does not require the VBE to enter into value-based arrangements with all such parties. For example, a VBE may enter into a services contract with a hospital that is not a VBE participant for the provision of items and services to the target patient population, although we note that the VBE must be at risk from the payor for the items and services provided by such hospital to the target patient population.

Accordingly, we do not view a hospital's participation in a value-based arrangement as a driver of industry consolidation; rather, we view the voluntary nature of a hospital's participation, as well as the voluntary participation of all other individuals or entities in a value-based arrangement, as facilitating collaboration and the transition to value-based care. Individuals and entities are not required to integrate their practices or corporations to meet the definition of ''VBE,'' to be a VBE participant, or to rely on this safe harbor. These definitions provide individuals and entities flexibility to determine how best to structure a VBE and the associated value-based arrangements to meet value-based purposes. VBEs and VBE participants that assume full financial risk from a payor and enter into value-based arrangements that meet the conditions of this safe harbor likely require different, more closely coordinated arrangements than VBEs and VBE participants that rely on the care coordination arrangements safe harbor. However, both sets of entities have flexibility to determine with what types of VBE participants to work and what types of arrangements work best.

ii. Items and Services

Summary of OIG Proposed Rule: We proposed to define ''items and services'' at paragraph 1001.952(gg)(9)(ii) as having the same meaning as that set forth in paragraph 1001.952(t)(2)(iv).

Summary of Final Rule: We are finalizing, with modification, the proposed definition of ''items and services'' at paragraph 1001.952(gg)(9)(iii) to mean health care items, devices, supplies, and services.

Comment: A commenter expressed concern that the proposed definition of ''items and services'' would inadvertently exclude arrangements that the health care industry views as full risk because ''items and services'' was defined to include services reasonably related to the provision of health care items, devices, supplies, or services, including, but not limited to, non-emergency transportation, patient education, attendant services, social services (*e.g.,* case management), utilization review and quality assurance. According to the commenter, the scope of ''items and services'' could add significant potential costs to parties seeking protection under the safe harbor. The commenter recommended that OIG revise the definition of ''items and services'' to include covered medical items and services but not items and services more in the nature of optional supplemental benefits.

Response: In response to the commenter's concerns, we are modifying the proposed definition of ''items and services'' to mean only health care items, devices, supplies, and services. We are no longer cross-referencing and incorporating the definition of ''items and services'' found in paragraph 1001.952(t)(2)(iv). Thus, a VBE *may* assume risk for items and services reasonably related to the provision of health care items, devices, supplies, or services such as non-emergency transportation, patient education, and social services (as provided for in the definition of ''items and services'' found in paragraph 1001.952(t)(2)(iv)), but doing so is no longer a safe harbor requirement.

The scope of items and services for which a VBE must be at risk depends on the items and services covered by the payor. We recognize that, across the health industry, what constitutes full risk for health care items, devices, supplies, and services varies greatly from program to program and plan to plan, and we have tailored this safe harbor requirement accordingly. For example, Medicare Advantage generally does not cover items and services for long-term care at nursing facilities, but Medicaid does. This safe harbor does not change the scope of items and services a payor must cover in order for a VBE to meet the definition of ''full financial risk.''

As we explained in the OIG Proposed Rule, a VBE would be at ''full financial risk'' if it contracts or enters into a value-based arrangement with a Medicaid managed care organization and receives a fixed per-patient per-month amount to be at full financial risk if the fixed amount covered the cost of all items and services covered by the Medicaid managed care plan and furnished to the target patient population. Similarly, we would consider a VBE to be at ''full financial risk'' if it contracts or enters into a value-based arrangement with a Medicare Advantage plan to receive a prospective, capitated payment for all items and services covered by the

Medicare Advantage plan for a target patient population. Under this safe harbor, we are not protecting partial capitated arrangements that require the VBE to assume risk for only a limited set of items and services.

Parties may utilize OIG's advisory opinion process to determine whether an arrangement meets the conditions of this safe harbor or is otherwise sufficiently low risk under the Federal anti-kickback statute to receive prospective immunity from administrative sanctions by OIG.

Comment: While recognizing that the proposed definition of ''full financial risk'' ties risk to payor coverage, a commenter requested that OIG explicitly state the extent to which medication costs may be included in the items and services for which a VBE must be at risk under the safe harbor. Another commenter stated that, if prescription drugs are included in the definition of all items and services for purposes of the full financial risk safe harbor, it is important that pharmaceutical manufacturers be eligible to participate in the VBE.

Response: To the extent the payor with which the VBE contracts to assume full financial risk covers prescription drugs, the VBE's risk must encompass prescription drugs. The definition of ''full financial risk'' requires that the VBE assume financial responsibility on a prospective basis for the cost of *all* items and services covered by the applicable payor for each patient in the target patient population. Conversely, if the contracting payor does not cover prescription drugs, the VBE does not need to assume risk for such costs.

While we recognize that prescription drugs may be included in the definition of ''full financial risk,'' manufacturers of a drug or biological remain ineligible to give or receive protected remuneration under this safe harbor as finalized here. Such parties may be VBE participants, but they cannot exchange remuneration protected by this safe harbor. We refer readers to the section of this final rule addressing the definition of ''VBE participant'' for a discussion of our rationale.

iii. Other Defined Terms

Summary of OIG Proposed Rule: We proposed in proposed paragraph 1001.952(gg)(9) that the terms ''coordination and management of care,'' ''target patient population,'' ''value-based activity,'' ''value-based arrangement,'' ''value-based enterprise,'' ''value-based purpose,'' and ''VBE participant'' would have the meaning set forth in proposed paragraph 1001.952(ee).

Summary of Final Rule: We are finalizing, with modifications, our proposed use of the value-based terminology at paragraph 1001.952(gg)(9)(iv). We no longer use the term ''coordination and management of care'' in this safe harbor. Additionally, because paragraph 1001.952(gg)(1) makes certain entities ineligible to use the value-based safe harbors, we are finalizing the term ''manufacturer of a device or medical supply,'' with the same meaning set forth in paragraph 1001.952(ee)(14).

c. Entities Ineligible for Safe Harbor Protection

Summary of OIG Proposed Rule: We proposed in proposed paragraph 1001.952(ee) to limit the entities that could qualify as VBE participants, which would have the effect of limiting availability of the value-based safe harbors, including the full financial risk safe harbor at proposed paragraph 1001.952(gg), for those ineligible entities. The proposed definition of ''VBE participant'' is summarized more fully in section III.B.2.e of this preamble.

Summary of Final Rule: We are not finalizing our proposal in proposed paragraph 1001.952(ee) to limit the entities that could qualify as VBE participants. As explained at section III.B.2.e, in the final rule we are identifying parties ineligible to rely on safe harbors in the safe harbors themselves. For the full financial risk safe harbor, we are finalizing a requirement that remuneration is not exchanged by any of the following entities: (i) Pharmaceutical manufacturers, wholesalers, and distributors; (ii) PBMs; (iii) laboratory companies; (iv) pharmacies that primarily compound drugs or primarily dispense compounded drugs; (v) manufacturers of devices or medical supplies; (vi) entities or individuals that manufacture, sell, or rent DMEPOS (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible); and (vii) medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies. This list, set forth at paragraph 1001.952(gg)(1), effectuates proposals in the OIG Proposed Rule to make these entities ineligible to use this safe harbor for the exchange of remuneration pursuant to a value-based arrangement.

Comments, our responses, and policy decisions regarding this issue can be found in the discussion of VBE participants in section III.B.2.e of this preamble.

d. VBE's Assumption of Risk From a Payor

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(1)that the VBE must assume full financial risk from a payor. We proposed that VBEs could assume full financial risk directly from a payor or through a VBE participant acting on behalf of the VBE.

Summary of Final Rule: We are finalizing this requirement at paragraph 1001.952(gg)(2), with the following modifications. First, VBEs have two options to assume full financial risk from a payor. A VBE can assume risk from the payor through an arrangement that meets the definition of ''value-based arrangement,'' or a VBE can assume risk from a payor through a contract that places the VBE at full financial risk.

The first option for risk arrangements requires the payor to be a VBE participant, which is permitted under our final definition of ''VBE participant.'' The payor (as a VBE participant) and the VBE can enter into a value-based arrangement for the VBE to assume full financial risk. As we proposed and are finalizing in this rule, the introductory paragraph to 1001.952(gg) protects remuneration exchanged pursuant to a value-based arrangement. Therefore, remuneration exchanged pursuant to a payor's and a VBE's value-based arrangement could be protected by this safe harbor, including remuneration exchanged to implement the full financial risk methodology, if the value-based arrangement meets all applicable conditions of the safe harbor.

Under the second option, payors that do not wish to be part of the VBE may choose to enter into a written contract with the VBE that is not a value-based arrangement for the purposes of the VBE's assumption of full financial risk. Under this option, payors would not be VBE participants, the written contract between the payor and the VBE would not be a value-based arrangement, and the payor would not be subject to the other conditions of the safe harbor. In such circumstances, these contracts must only meet the condition at paragraph 1001.952(gg)(2), *i.e.,* they must evidence the VBE's assumption of full financial risk from the payor. Remuneration exchanged pursuant to a risk assumption contract that is not a value-based arrangement is not protected by this safe harbor. The VBE and the payor would need to assess any potential remuneration exchanged pursuant to the risk arrangement contract and its compliance with the Federal anti-kickback statute.

To enable the payor and VBE to use this safe harbor to protect remuneration exchanged pursuant to their value-based arrangement, we are providing at paragraph 1001.952(gg)(4) of the safe harbor that, even though the payor is a VBE participant, the payor is exempt from the prohibition against a VBE participant claiming payment in any form from the payor for items or services covered under the value-based arrangement.

We are also modifying this requirement to clarify that the payor cannot act on behalf of the VBE; the VBE must be a distinct legal entity or represented by a VBE participant, other than a payor, that acts on the VBE's behalf.

We summarize and respond to comments regarding this proposed condition as applied only to the full financial risk safe harbor below. For a summary of the comments received regarding the requirement that a VBE assume financial risk from a payor pursuant to a value-based arrangement, in both the substantial downside financial risk and full financial risk safe harbors and our responses, we refer readers to the discussion of this condition in the substantial downside financial risk safe harbor at section III.B.4.d.

Comment: Commenters requested that OIG clarify that payors can act on behalf of the VBE to assume full financial risk.

Response: We are revising the regulatory text in response to these comments to clarify that a single VBE participant may act on behalf of the VBE to assume full financial risk from a payor, provided it is not itself a payor. That is, the agent of the VBE and the payor from which the VBE is assuming full financial risk from may not be the same entity.

Comment: Multiple commenters expressed concern that, because Indian health care is compensated through Indian Health Service appropriations and the Medicare, Medicaid, and CHIP programs, Indian health care providers could not be risk-bearing entities, as required in the proposed full financial risk safe harbor.

Response: It is possible that Indian health care providers might not be risk-bearing entities for purposes of this safe harbor; that would be a programmatic matter outside the scope of this rulemaking. There may be other providers of varying types that are not able to, or choose not to, meet the requirements of this safe harbor. This would not foreclose Indian health care providers or other providers from engaging in care coordination arrangements and seeking safe harbor protection under the care coordination arrangements safe harbor at paragraph 1001.952(ee), which does not require the assumption of any risk (but is available for risk-bearing arrangements), or other available safe harbors, such as the safe harbor for personal services and management contracts and outcomes-based payments at paragraph 1001.952(d). Moreover, the fact that an arrangement does not fit in a safe harbor does not make the arrangement unlawful. The OIG advisory opinion process is also available for providers seeking a legal opinion regarding their arrangements.

Comment: A commenter requested that the safe harbor not be limited to items and services covered by a particular payor, but rather extended to all items and services provided to a VBE participant's patients, regardless of payor. For example, the commenter requested that the safe harbor protect risk-based arrangements between a health system and providers where the VBE assumes risk for all of the providers' patients, regardless of the patients' payors.

Response: A VBE could assume full financial risk for all of the items and services provided to all of a VBE participant's patients, provided the VBE and VBE participant have defined the target patient population to include all of the VBE participant's patients, and if the VBE participant's patients are insured by multiple payors, the VBE has assumed full financial risk from each payor that insures a patient who is part of the target patient population. The risk that a VBE assumes is not limited to the items and services covered by the applicable payor that a VBE participant provides (*e.g.,* only the items and services provided by the health system); rather, the VBE's risk encompasses all items and services covered by the applicable payor, regardless of whether a VBE participant or another provider provides such items and services.

e. Phase-In Period

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(1) that the full financial risk safe harbor would protect remuneration exchanged pursuant to value-based arrangements between a VBE and a VBE participant where the VBE is contractually obligated to assume full financial risk in the next 6 months. We solicited comments on whether such lead time should be shorter or longer.

Summary of Final Rule: We are finalizing, with modification, a protected ''phase-in'' period at paragraph 1001.952(gg)(2). In response to comments requesting a longer phase-in period, we are extending the protected phase-in period for parties that have entered into a contract or a value-based arrangement to assume full financial risk from the proposed 6 months to 1 year.

In contrast to the substantial downside financial risk safe harbor, we believe an extended 1-year phase-in period is warranted where a VBE is preparing to assume full financial risk for the total cost of items and services covered by the applicable payor for the target patient population.

We refer readers to the substantial downside financial risk safe harbor section at III.B.4.e regarding the phase-in requirement for a summary of comments we received on this phase-in period, and our responses, as applicable to both the substantial downside financial risk safe harbor and full financial risk safe harbor and for a more detailed discussion of this standard. We did not receive comments regarding the phase-in period specific to the full financial risk safe harbor. Among other comments, commenters recommended a 1-year phase-in period for both safe harbors.

f. Writing

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(2) that the parties to the value-based arrangement must set forth the material terms of the value-based arrangement in a signed writing that includes the value-based activities to be undertaken by the parties. At proposed paragraph 1001.952(gg)(1), we proposed that the VBE have a signed writing with the payor that specifies the target patient population and contains terms evidencing the VBE's full financial risk.

Summary of Final Rule: We are finalizing, with modification, a writing requirement for value-based arrangements at paragraph 1001.952(gg)(3). The modification, based on public comments, clarifies that the writing requirement can be satisfied by a collection of documents. The writing requirement now states that the value-based arrangement must be set forth in writing, signed by the parties, and specify all material terms, including the value-based activities and the term. This writing requirement does not apply to contracts between a VBE and a payor that are not value-based arrangements.

For further discussion of and responses to the general comments we received regarding a writing requirement, we refer readers to section III.B.3.d that discusses the writing requirement for purposes of the care coordination arrangements safe harbor. The general comments addressed

aspects of the writing requirement that were common to all three value-based safe harbors. In this section, we discuss only the comments specific to the proposed full financial risk safe harbor's writing requirement.

Comment: A commenter asked OIG to clarify whether, to the extent parties have multiple value-based arrangements for which they are seeking protection under this safe harbor, each value-based arrangement must be set forth in separate writings or whether one agreement could suffice.

Response: This safe harbor, like the substantial downside financial risk safe harbor, does not dictate the manner in which parties document their value-based arrangements. For example, a VBE could choose to document the value-based arrangement it entered into with a payor and the value-based arrangement it entered into with a downstream VBE participant in a single writing; alternatively, it could maintain two separate writings for the two distinct value-based arrangements.

g. 1-Year Minimum Term of Value-Based Arrangement

Summary of OIG Proposed Rule: In the OIG Proposed Rule, we proposed in paragraph 1001.952(gg)(2) to require that the term of the value-based arrangement be for a period of at least 1 year.

Summary of Final Rule: We are not finalizing this proposed requirement.

Comment: A few commenters opposed the proposed requirement that the term of the value-based arrangement be for at least 1 year, with one commenter asserting that a value-based arrangement term requirement could impose unnecessary obstacles to beneficial innovation. Commenters also asked whether an arrangement would meet this requirement of the safe harbor if the parties terminate the arrangement during the first year but do not enter into a substantially similar arrangement until the expiration of the first year.

Response: We are not finalizing the proposed requirement that the term of the value-based arrangement be for a period of at least 1 year. We believe the requirement for a VBE to assume full financial risk from the payor for a period of at least 1 year is a sufficient safeguard against gaming without also requiring the value-based arrangement to have a 1-year minimum term. Parties must still document the term of their value-based arrangement as a condition of meeting this safe harbor's writing requirement.

h. Remuneration Used To Engage in Value-Based Activities

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(4)(i) to require that the remuneration exchanged be used primarily to engage in the value-based activities set forth in the parties' signed writing.

Summary of Final Rule: We are not finalizing this proposed requirement.

Comment: A commenter asked whether, given the requirement that remuneration must be used primarily to engage in value-based activities, all activities of an integrated delivery system subject to global budget arrangements, either upstream or downstream, will relate to the value-based activities for the target patient population. Another commenter requested that we interpret this requirement to mean that, if substantially all of an integrated delivery system's activities include the assumption of financial risk for all services, the remaining incidental activities and associated remuneration among VBE participants also would be protected.

Response: We are not finalizing the proposed requirement that all remuneration exchanged pursuant to the full financial risk safe harbor be used primarily to engage in value-based activities for the target patient population. We intended this proposed condition to safeguard against the exchange of remuneration to inappropriately induce referrals. However, based on comments received to this safe harbor and the substantial downside financial risk safe harbor (as detailed in section III.B.4.f), we do not think this safeguard is necessary in the full financial risk safe harbor, given this safe harbor's unique combination of safeguards, and in particular, the requirement that the VBE assume full financial risk from a payor for a target patient population and the safe harbor's limitation on exchanges of remuneration to those between the VBE and a VBE participant. For purposes of the substantial downside financial risk safe harbor, we addressed this issue more narrowly, excluding monetary remuneration exchanged pursuant to a risk methodology that meets the definition of ''substantial downside financial risk'' or ''meaningful share'' from the requirement that remuneration exchanged be used predominantly to engage in value-based activities. However, for the reasons set forth above, we believe a more flexible approach is warranted in this safe harbor, and we are not finalizing the proposed condition.

With respect to the comment regarding safe harbor protection for incidental activities and associated remuneration where substantially all of an entity's activities include the assumption of financial risk for all services, we note that the value-based safe harbors do not protect business models or necessarily all activities and remuneration flowing under, for example, an integrated delivery system. Rather, the full financial risk safe harbor, like the other value-based safe harbors, protects discrete streams of remuneration exchanged pursuant to a value-based arrangement, and parties would need to evaluate each stream separately to assess compliance with the Federal anti-kickback statute, and as applicable, any available safe harbor.

i. Direct Connection to Value-Based Purposes

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(4)(ii) to require that the remuneration be directly connected to one or more of the VBE's value-based purpose(s), at least one of which must be the coordination and management of care for the target patient population. We proposed that this condition would be interpreted consistent with the similar condition in the care coordination arrangements safe harbor.

Summary of the Final Rule: We are finalizing, with modification, the requirement that remuneration exchanged between the VBE and a VBE participant under this safe harbor be connected to one or more value-based purposes at paragraph 1001.952(gg)(5)(i). Based on public comment, we are modifying the provision to remove the requirement that all remuneration be connected to the purpose of coordinating and managing care for the target patient population.

Comment: Commenters asked for examples of the types of arrangements the safe harbor could protect, and a commenter specifically asked whether the safe harbor would protect fee-for-service payments, bonus payments based on quality outcomes, or both from a VBE to a VBE participant. A commenter also asked whether a VBE could give remuneration to an owner of the VBE, where the owner is a VBE participant.

Response: This safe harbor could protect arrangements for bonus payments based on quality outcomes or shared savings and losses arrangements, among other types of payment arrangements, as long as all requirements of the safe harbor are satisfied, including the requirement that

the remuneration exchanged must be directly connected to one or more value-based purposes. With respect to the commenter's question about fee-for-service payment, this safe harbor does not dictate the manner of payment between the VBE and the VBE participant for items and services rendered to the target patient population. Provided the VBE has assumed full financial risk from a payor and the VBE participant does not claim payment from the payor for the items and services furnished to the target patient population, the VBE could pay the VBE participant on a fee-for-service basis.

Whether a VBE could give remuneration to an owner of the VBE, where the owner is a VBE participant, is a fact-specific determination. While the safe harbor, by its terms, does not preclude remuneration exchanged between a VBE and an owner of the VBE where the owner is a VBE participant, we highlight that this safe harbor does not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest.

Unlike the similar requirement in the other value-based safe harbors, we are not requiring a direct connection to any specific value-based purpose under this safe harbor. This safe harbor is designed to protect the broadest scope of remuneration, and some remuneration may be more closely connected to one of the other value-based purposes. Therefore, we are providing more flexibility for a VBE assuming full financial risk to determine the value-based purpose(s) to which the exchange of remuneration is directly connected. This includes remuneration exchanged pursuant to a value-based arrangement between the VBE and the payor (as a VBE participant) that effectuates the VBE's assumption of full financial risk from the payor. For a summary of comments received regarding the requirement for a direct connection to the coordination and management of care and further discussion of this requirement as proposed in the care coordination arrangements safe harbor, the substantial downside financial risk safe harbor, and the full financial risk safe harbor, we refer readers to the applicable section of this final rule for each safe harbor.

j. No Reduction in Medically Necessary Items or Services

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(4)(iii) to require that remuneration must not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient. We proposed to interpret this condition consistent with the similar condition proposed in the care coordination arrangements safe harbor.

Summary of Final Rule: We are finalizing, with modification, this condition at paragraph 1001.952(gg)(6). The modification provides that the value-based arrangement (not merely the remuneration exchanged) may not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient.

For a summary of comments received and our responses regarding this condition, as proposed in each of the value-based safe harbors, we refer readers to the care coordination arrangements and substantial downside financial risk safe harbor sections discussing this requirement at III.B.3.e and III.B.4.h, respectively.

k. Taking Into Account the Volume or Value of, or Conditioning Remuneration on, Business or Patients Not Covered Under the Value-Based Arrangement

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(5) that the VBE or VBE participant offering the remuneration could not take into account the volume or value of, or condition the remuneration on, referrals of patients outside of the target patient population or business not covered under the value-based arrangement. This proposed safeguard is identical to that included in the proposed care coordination arrangements and substantial downside financial risk safe harbors.

Summary of Final Rule: We are finalizing, without modification, this condition, and relocating it to paragraph 1001.952(gg)(7). Comments received on this topic addressed the requirement as it applied to the value-based safe harbors generally; we did not receive separate comments on this requirement specific to this safe harbor. Consequently, we refer readers to the care coordination arrangements safe harbor section regarding this requirement at III.B.3.f for a summary of applicable comments, our responses, and a more detailed discussion of this standard.

l. Offer or Receipt of Ownership or Investment Interests

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(4)(iv) that the full financial risk safe harbor would not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest, and we solicited comments on this approach and, in particular, any operational challenges this approach might present.

Summary of Final Rule: We are finalizing, without modification, this condition and relocating it to paragraph 1001.952(gg)(5)(ii).

Comment: Similar to the substantial downside financial risk safe harbor, several commenters opposed this condition or, alternatively, requested that OIG clarify that it does not intend to prohibit VBE participants from establishing a corporate structure for a VBE in which participants may each receive some equity. A commenter asserted that, without modifying or clarifying OIG's approach to protecting an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest, the safe harbor would unnecessarily restrict individuals and entities from dictating the corporate structure of the VBEs they elect to create. Another commenter stated that the safe harbor should protect ownership or investment interests where payors require that only a single entity, as opposed to a collection of entities, enter into the full financial risk arrangement.

Response: We do not view protection for ownership or investment interests in a VBE as fundamental to parties entering into value-based arrangements under this safe harbor and decline to protect them under this safe harbor. We are concerned that, were we to protect such remuneration streams, such protection would serve only to align financial interests of the parties without benefitting the payor or target patient population. Remuneration in the form of ownership or investment interests presents a higher risk that offers of investment interests or returns on investment will be for the purpose of inducing referrals, without attendant care coordination, quality, or cost-reduction benefits related to the target patient population or the payor. Parties seeking to protect a particular ownership or investment interest may look to existing safe harbors (*e.g.,* the safe harbor for investment interests found at paragraph 1001.952(a)), and the advisory opinion process remains available.

Regardless of whether a payor requires that a single entity, as opposed to a collection of entities, enter into a contract or a value-based arrangement to assume full financial risk, the safe harbor itself requires a single individual or entity to contract or enter into a value-based arrangement with the payor to assume full financial risk (*e.g.,* the VBE may directly contract with the

payor or a single VBE participant (other than a payor) may act on behalf of the VBE to contract with the payor). If a VBE participant that has assumed full financial risk as an agent of the VBE seeks to share its risk with other parties to the VBE, the safe harbor is available to protect such risk-sharing arrangements, provided they meet all requirements of the safe harbor.

m. No Remuneration From Individuals or Entities Outside the Applicable VBE

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(4)(v) that the full financial risk safe harbor would not protect any remuneration funded by, or otherwise resulting from contributions by, any individual or entity outside of the applicable VBE.

Summary of Final Rule: We are not finalizing this proposed requirement, based on concerns—raised by commenters in the context of the same provision in the care coordination arrangements safe harbor—that this condition could inadvertently restrict the exchange of beneficial remuneration that we intend to protect. While we are not finalizing this condition, we emphasize that remuneration exchanged outside of a value-based arrangement would not be protected by any of the value-based safe harbors. We did not receive separate comments on this requirement specific to this safe harbor. Consequently, we refer readers to the care coordination arrangements safe harbor and substantial downside financial risk safe harbor sections at III.B.3.e and III.B.4.j discussing this requirement for a summary of applicable comments, our responses, and a more detailed explanation of our rationale for not finalizing this standard.

n. Utilization Review and Quality Assurance Programs

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(6) that the VBE must provide or arrange for an operational utilization review program and a quality assurance program that protects against underutilization and specifies patient goals, including measurable outcomes, where appropriate. We noted that such proposed conditions would mirror those found in the managed care safe harbor at paragraph 1001.952(u) but explained that we were considering other ways to frame these proposed conditions to reflect the utilization review and quality assurance mechanisms in place today.

Summary of Final Rule: We are finalizing, with modifications, this proposed condition at paragraph 1001.952(gg)(8). Based on public comment, the modifications afford parties additional flexibility in conducting quality and utilization reviews. Specifically, VBEs seeking protection under this safe harbor must provide or arrange for a quality assurance program for services furnished to the target patient population that: (i) Protects against underutilization of items and services furnished to the target patient population; and (ii) assesses the quality of care furnished to the target patient population. We are not finalizing the proposed requirement to have an operational utilization review program.

Comment: Some commenters supported our proposal to require the VBE to provide or arrange for an operational utilization review program and a quality assurance program, while another commenter requested that OIG reconsider this requirement, stating that VBEs are not the equivalent of a managed care organization and that operational utilization review programs and quality assurance programs are robust, expensive programs that require significant lead time to implement. A couple of commenters asked OIG to explain the term ''operational,'' and a commenter specifically asked whether a utilization review program that is used only on an annual basis would be considered ''operational.'' Another commenter asked whether an existing utilization review program of a contracting payor or provider would meet this requirement.

Response: We are revising the terminology used in order to afford parties additional flexibility consistent with our intent that a VBE provide or arrange for a program to protect against underutilization and specify patient goals. Specifically, VBEs must provide or arrange for a quality assurance program for services furnished to the target patient population that: (i) Protects against underutilization of items and services furnished to the target patient population; and (ii) assesses the quality of care furnished to the target patient population. Such a quality assurance program may include an operational utilization review program and specify patient goals; however, an operational utilization review program is no longer a requirement. Pursuant to this revised standard, parties may determine what activities and mechanisms are most suitable to assess the quality and appropriateness of care furnished to the target patient population, provided such mechanisms meaningfully protect against underutilization and assess the quality of care furnished to the target patient population.

The flexibility we are providing to parties is in recognition that VBEs may be subject to varying requirements related to quality assurance programs based on State law or the terms of its value-based arrangement with the payor. Notwithstanding this additional flexibility, as with the condition proposed in the OIG Proposed Rule, this revised requirement effectuates our intent that a VBE provide or arrange for a program to protect against underutilization and specify patient goals.

In response to commenters' specific inquiries, we acknowledge that, even with the additional flexibility afforded by our revisions to this condition, quality assurance programs are robust and potentially expensive undertakings. Thus, we are highlighting that this condition does not mandate that VBEs establish such review programs themselves; the VBE may also arrange for such programs. For example, VBEs may look to payors with which they are contracting or entering into value-based arrangements to assume full financial risk to share, or fully assume, this responsibility. In such circumstances, the VBE may reasonably rely on the payor's existing quality assurance program infrastructure provided it meets all safe harbor requirements.

o. No Marketing of Items or Services or Patient Recruitment Activities

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(7) to exclude safe harbor protection for remuneration exchanged pursuant to a value-based arrangement that included marketing items or services to patients or engaging in patient recruitment activities. We proposed to interpret this condition consistent with our interpretation of this same proposed requirement in the care coordination arrangements safe harbor.

Summary of Final Rule: We are finalizing, with modifications, the limitation on marketing and patient recruitment at paragraph 1001.952(gg)(5)(iii). Rather than prohibiting all marketing and patient recruitment activities, we modified the provision to prohibit the exchange or use of remuneration for the purpose of marketing items or services furnished by the VBE or VBE participants to patients or for the purpose of patient recruitment activities. We received only one comment on this requirement specific to this safe harbor, detailed below. We refer readers to the care coordination arrangements safe harbor's discussion regarding this requirement at section III.B.3.j for a summary of applicable comments, our responses, additional

explanation regarding this standard, and a rationale for the modification we are making.

Comment: Without further explaining its position, a commenter stated that there is no need for any marketing or patient recruitment limitations in the full financial risk safe harbor.

Response: Consistent with the other value-based safe harbors, we have modified the marketing requirement to be more limited in scope but to preclude protection for remuneration exchanged or used for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or patient recruitment activities. Although we agree that the VBE's assumption of full financial risk generally warrants greater flexibility in this safe harbor, we continue to believe that a prohibition on certain marketing and patient recruitment practices is an important fraud and abuse safeguard across all three value-based safe harbors for the reasons set forth in the discussion of the marketing condition in the care coordination arrangements safe harbor. In particular, with respect to the full financial risk safe harbor, we are concerned that remuneration under the value-based arrangement may be exchanged or used to engage in inappropriate patient recruitment activities to incentivize, for example, beneficiary enrollment in, or alignment to, a particular health plan.

p. Materials and Records

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(gg)(8) that the VBE or its VBE participants maintain documentation sufficient to demonstrate compliance with the safe harbor's conditions and to make such records available to the Secretary upon request. We solicited comments regarding whether we should require parties to maintain materials and records for a set period of time (*e.g.,* at least 6 years or 10 years). We proposed to interpret this requirement as described in the OIG Proposed Rule's preamble discussing the proposed care coordination arrangements safe harbor.

Summary of Final Rule: We are finalizing, with modification, the materials and records requirement at paragraph 10001.952(gg)(9). The final rule includes new language to specify that, for a period of at least 6 years, the VBE or its VBE participants must maintain materials and records sufficient to establish compliance with the conditions of the safe harbor. We did not receive separate comments on this requirement specific to this safe harbor; the comments received related to the value-based safe harbors generally. Consequently, for a more detailed discussion and a summary of and responses to the comments received regarding this requirement, we refer readers to section III.B.3.n discussing the materials and records condition in the care coordination arrangements safe harbor.

q. Downstream Arrangements

Summary of OIG Proposed Rule: In the preamble, we noted that the proposed full financial risk safe harbor would apply only to remuneration exchanged between a VBE and a VBE participant pursuant to a value-based arrangement. We stated that the proposed safe harbor would not protect remuneration exchanged between or among VBE participants that are part of the same VBE, between a VBE participant and a downstream contractor, or between two downstream contractors. We explained that we were concerned about extending safe harbor protection to remuneration exchanged pursuant to these arrangements because the downstream parties may have assumed little or no financial risk, which could result in fee-for-service incentives, and therefore, a risk of overutilization or other traditional harms associated with fee-for-service payments. We solicited comments on a variety of alternate approaches to protecting remuneration exchanged pursuant to certain downstream arrangements (*e.g.,* additional safeguards in either the full financial risk safe harbor or another safe harbor).

Summary of Final Rule: We are finalizing, without modification, the requirement that the exchange of remuneration must be between the VBE and a VBE participant in the introductory paragraph to 1001.952(gg). We are not extending safe harbor protection to remuneration that passes from one VBE participant to another VBE participant or a downstream contractor. As articulated in the substantial downside financial risk safe harbor section discussing downstream arrangements, we are limiting safe harbor protection to the exchange of remuneration between the VBE and a VBE participant because we believe it is important to provide the protection and regulatory flexibility the risk-based safe harbors afford only where the VBE is a party to the value-based arrangement. We are concerned that, without the VBE as a party, where neither party has assumed full financial risk and may continue to bill the applicable payor on a fee-for-service-basis, there is a heightened concern about traditional FFS fraud and abuse risks. We note that a VBE participant seeking to exchange remuneration with another VBE participant may look to the care coordination arrangements safe harbor or other safe harbors, such as the personal services and management contracts and outcomes-based payments safe harbor.

For a summary of the comments received regarding this limitation, our responses, and a detailed explanation regarding our decision not to extend this safe harbor to downstream arrangements, we refer readers to our discussion of the parallel provision in the substantial downside financial risk safe harbor in section III.B.4.p. We did not receive comments on this requirement specific to this safe harbor that diverged from the comments summarized in the section describing the parallel provision in the substantial downside financial risk safe harbor.

r. Potential Additional Safeguards

Summary of OIG Proposed Rule: We stated in the preamble that we were considering adopting two additional safeguards for purposes of the final rule: A cost-shifting prohibition and a requirement that parties submit information to the Department regarding their value-based arrangement.

Summary of Final Rule: We are not finalizing the two additional proposed safeguards. Similar to the substantial downside financial risk safe harbor, we are not including a cost-shifting prohibition, in recognition that the assumption of full financial risk is intended to drive a reduction in costs, which may include Federal health care program costs. We did not receive comments on this alternative condition specific to this safe harbor that diverged from the comments summarized in section III.B.4.q of the substantial downside financial risk safe harbor preamble, and we refer readers to that section for a summary of comments received and our responses.

We are likewise not finalizing a requirement for parties to submit information to the Department for the reasons previously articulated in the care coordination arrangements safe harbor's discussion of this alternative safeguard, including minimizing administrative burden. We did not receive comments on this condition specific to this safe harbor that diverged from the comments previously summarized in section III.B.4.p of the care coordination arrangements safe harbor preamble, and we refer readers to that section for a summary of comments and our responses.

We received comments requesting additional safeguards to the full financial risk safe harbor that we did not

propose, and we summarize such comments below.

Comment: Several commenters supported the addition of other safeguards that we did not propose in the preamble to the full financial risk safe harbor. For example, some commenters supported a requirement for value-based arrangements to include objective and quantifiable outcome measures, and a commenter asserted that the outcome measures, the methodology for measuring them, and how the measures affect cost should be transparent to the public. Other commenters suggested that we include the requirement that neither the value-based arrangement nor VBE participants limit parties' ability to make decisions in the best interest of their patients.

Response: We are not requiring, in the context of the full financial risk safe harbor, that value-based arrangements include outcome measures (or any public transparency requirements related to such outcome measures) because we did not propose this as a requirement, and we do not believe that such a requirement would appreciably mitigate risk, given other conditions of the safe harbor. However, we note that we are separately requiring that the VBE provide or arrange for a quality assurance program for services furnished to the target patient population that: (i) Protects against underutilization of items and services furnished to the target patient population; and (ii) assesses the quality of care furnished to the target patient population. While outcome measurement is not a requirement of this safe harbor, as a practical matter, we anticipate that an assessment of the quality of care furnished to the target patient population pursuant to a quality assurance program may include quantitative or qualitative measures assessing, for example, performance on certain outcome measures. We did not propose and are not finalizing a requirement that neither the value-based arrangement nor VBE participants limit the parties' ability to make decisions in the best interest of their patients, nor do we think it would be necessary given other protections in the safe harbor.

6. Arrangements for Patient Engagement and Support To Improve Quality, Health Outcomes, and Efficiency (42 CFR 1001.952(hh))

Summary of OIG Proposed Rule: We proposed to establish a new safe harbor at paragraph 1001.952(hh) to protect remuneration in the form of patient engagement tools and supports furnished directly by VBE participants to patients in a target patient population. The tools and supports could not be funded by anyone outside the VBE (proposed paragraph 1001.952(hh)(2)). We proposed to protect only in-kind preventive items, goods, or services, or in-kind items, goods, or services, such as health-related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health (proposed paragraph 1001.952(hh)(3)(i)). We proposed that protected remuneration would need to have a direct connection to the coordination and management of care (proposed paragraph 1001.952(hh)(3)(ii)) and advance one of six enumerated goals related to patient care (proposed paragraph 1001.952(hh)(3)(vii)). The proposal included a $500 cap on the amount of protected remuneration a VBE participant could furnish to a patient on an annual basis, with an exception based on the good faith, individualized determination of a patient's financial need (proposed paragraph 1001.952(hh)(5)). The proposed safe harbor included several additional conditions, such as a requirement that provision of a tool or support would not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program. Other proposed conditions are summarized more fully below.

Summary of Final Rule: We are finalizing, with modifications, the patient engagement and support safe harbor at paragraph 1001.952(hh). The bases for the modifications are explained the preamble sections that follow. In particular, we have revised the language at paragraph 1001.952(hh)(3)(i) to remove the specific illustrative categories of health-related technologies, patient health-related monitoring tools and services, and supports and services designed to identify and address a patient's social determinants of health. With respect to preventive items, goods, and services, we have moved the element of prevention to the list of enumerated goals that can be advanced by protected remuneration at paragraph 1001.952(hh)(3)(vi). The final language at paragraph 1001.952(hh)(3)(i) articulates our policy to be agnostic as to the types of in-kind tools and supports that can be protected by the safe harbor if all safe harbor conditions are met.

Further, we are finalizing at paragraph 1001.952(hh)(1) a list of entities that may not furnish or otherwise fund or contribute to protected tools and supports under this safe harbor, which includes manufacturers, distributors, and wholesalers of pharmaceuticals; pharmacy benefit managers; laboratory companies; pharmacies that primarily compound drugs or primarily dispense compounded drugs; manufacturers of devices and medical supplies (unless the tool or support is digital health technology); entities or individuals that sell or rent DMEPOS (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services); medical device distributors and wholesalers; and physician-owned medical device companies. Similar to our approach in the care coordination arrangements safe harbor at paragraph 1001.952(ee), a tool or support furnished or funded by a manufacturer of a device or medical supply (as defined in paragraph 1001.952(ee)(14)) is eligible for safe harbor protection only if the tool or support is digital health technology (defined at paragraph 1001.952(ee)(14)). As explained at section III.B.2.e above, we are listing ineligible entities in each safe harbor rather than excluding them in the definition of VBE participant.

The final safe harbor protects only in-kind remuneration. The final safe harbor includes at paragraph 1001.952(hh)(5) the proposed $500 annual, aggregate cap provision (without the proposed exception for tools and supports above the cap furnished based on good faith, individualized determinations of a patient's financial need). The final safe harbor also includes at paragraph 1001.952(hh)(3)(iv) the proposed requirement that the provision of a tool or support not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program. Additional conditions of the final safe harbor are summarized by topic in discussions that follow.

a. General Comments

Comment: Among the commenters offering general feedback on the proposed safe harbor, some commenters supported the proposed safeguards, others supported adding some or all of the additional considered safeguards on which we solicited comments, and others stated that certain proposed or additional safeguards would impose a significant administrative burden on stakeholders seeking protection under the safe harbor. A number of comments noted that the safe harbor would promote patient engagement, encourage adherence to treatment, and improve outcomes. Other commenters requested

specific changes or clarifications to various proposals.

Response: We appreciate the commenters' suggestions regarding the scope and impact of this safe harbor, including the conditions we proposed and considered. As discussed below, we are finalizing a number of the proposed conditions, in some cases with modifications suggested by commenters. We also are removing or modifying some conditions in response to comments and adding some of the proposed conditions for which we solicited comments.

b. Entities Ineligible for Protection

Summary of OIG Proposed Rule: We proposed to protect only tools and supports furnished by VBE participants, as defined in proposed paragraph 1001.952(ee)(12). This proposed definition excluded pharmaceutical manufacturers, laboratories, and manufacturers, distributors, and suppliers of DMEPOS. As a result, these entities would be ineligible to use this proposed safe harbor. The entities we proposed to make ineligible to participate in a VBE are described in more detail in section III.B.2.e of this preamble. We also indicated that the final rule might exclude additional entities from furnishing patient engagement tools and supports, including physician-owned device companies, compounding pharmacies, and medical device and supply manufacturers, wholesalers, and distributors.[55] We solicited comments on several alternative frameworks for protected offerors and conditions related to protected offerors under this safe harbor, including whether the offeror should assume at least some downside financial risk.

Summary of Final Rule: As explained in section III.B.2.e of this preamble, the final definition of VBE participant has been expanded to make all entity types eligible as VBE participants. However, within each value-based safe harbor, we identify entities that are ineligible to rely on that particular safe harbor. For the patient engagement and support safe harbor, and as set forth in paragraph 1001.952(hh)(1), we are finalizing the following entities as ineligible to use the safe harbor to furnish protected remuneration to patients: (i) Pharmaceutical manufacturers, wholesalers, and distributors; (ii) PBMs; (iii) laboratory companies; (iv) pharmacies that primarily compound drugs or primarily dispense compounded drugs; (v) manufacturers of devices or medical supplies (except with respect to digital health technology, as described below); (vi) entities or individuals that sell or rent DMEPOS (other than a pharmacy, a medical device or supply manufacturer that also sells or rents DMEPOS, or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible); (vii) medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies; and (viii) medical device manufacturers, distributors, or wholesalers with ownership or investment interests held by physicians. This expanded list of excluded entities addresses our concerns, based on our longstanding enforcement and oversight experience, that certain types of entities present a higher risk of misusing this safe harbor primarily or significantly to offer remuneration to beneficiaries as a means to market their products and services rather than to improve the coordination and management of patient care.

In this final rule, OIG recognizes the important role that digital health technology plays in advancing the Department's goals in connection with the Regulatory Sprint, including improving the coordination and management of patient care. Accordingly, at paragraph 1001.952(hh)(1)(v), this final rule permits manufacturers of devices and medical supplies to furnish patient engagement tools or supports that constitute digital health technology, as defined at paragraph 1001.952(ee)(14). On balance and in consideration of the full set of applicable safe harbor conditions, we have concluded that this policy would advance the benefits of improved care coordination without undue risk to patients or programs.

With respect to whether an entity falls into a category of ineligible entities, we refer readers to the discussion of the various types of ineligible entities and entities with multiple lines of business at section III.B.2.e of this preamble. The same rationale set forth there for excluding each type of entity from the value-based safe harbors and the same analysis for categorizing entities with multiple lines of business apply to the patient engagement and support safe harbor.

Comment: A number of commenters supported OIG's proposal to limit safe harbor protection to tools and supports furnished by VBE participants, as defined in the OIG Proposed Rule, because it helps ensure that the tools and supports are aligned with the goals of well-coordinated care and improving value by incentivizing coordination and collaboration among a patient's providers. Commenters also supported making specific types of entities ineligible for protection under this safe harbor, such as pharmaceutical manufacturers and manufacturers, distributors, and suppliers of DMEPOS.

Response: We are finalizing our policy that safe harbor eligibility is limited to VBE participants and, consequently, that tools and supports furnished or funded by certain types of entities would not be eligible for safe harbor protection. The final patient engagement and support safe harbor protects only remuneration provided by a VBE participant; this term, as defined in this final rule, does not limit or restrict what type of entity may be a VBE participant. However, this safe harbor does not protect tools and supports furnished or funded by the entities listed in paragraph 1001.952(hh)(1), even if such entities are VBE participants.

We continue to believe that offering and furnishing patient engagement tools and supports by these ineligible entities elevates the risk of fraud and abuse. For example, as we stated in the OIG Proposed Rule, offers of tools or supports by pharmaceutical manufacturers to a patient could improperly influence the patient, as well as a clinician's decision to prescribe one drug over another. Such remuneration could influence a patient to request a particular drug that is more expensive or less clinically efficacious than other clinically equivalent drugs. This could both improperly influence patient choice and increase costs to Federal health care programs—two factors cited by Congress to consider when developing safe harbors—without necessarily increasing quality. Similarly, we remain concerned that the entities identified as ineligible for this safe harbor may inappropriately use patient engagement tools and supports to induce the use of medically unnecessary items and services; market their products; or divert patients from a more clinically appropriate item or service, provider, or supplier without regard to the best interests of the patient. Accordingly, we are finalizing paragraph 1001.952(hh)(1) to specify that the entities listed above are ineligible to furnish, fund, or contribute to remuneration protected by the patient engagement and support safe harbor.

Comment: Several commenters urged OIG to broaden the safe harbor to protect tools and supports offered by entities that are not VBE participants. Another commenter noted that many payors and providers have developed effective patient incentive programs that

[55] 84 FR 55703–06, 55722 (Oct. 17, 2019).

have occurred outside the value-based care setting but nonetheless advance OIG's goals of improving adherence to a followup care plan, improving adherence to a treatment or drug regimen, enhancing the management of a disease or condition, or ensuring patient safety. Commenters also expressed concern that requiring VBE participation imposes an increased administrative burden on providers, which could be a barrier to offering patient engagement tools and supports. Another commenter added that limiting the safe harbor to VBE participants would effectively preclude single-provider entities from safe harbor protection.

Response: As noted above, we are finalizing a condition that safe harbor protection is only available for tools and supports furnished by VBE participants, subject to additional conditions. In the preamble to the OIG Proposed Rule, we explained that safe harbor protection would only be available to VBE participants in order to align the proposed patient engagement and support safe harbor with the value-based framework proposed in that rule.[56] Limiting safe harbor protection to VBE participants is an important condition because it requires entities to adhere to certain formalities that promote value-based objectives including, for example, articulating a value-based purpose and identifying a target patient population based on legitimate and verifiable criteria that are set out in writing and further the VBE's value-based purpose.

Moreover, we believe the modest administrative steps required to establish a VBE—namely, establishing an accountable body and creating a governing document—require that entities determine how to effectively promote value-based care (*e.g.,* how the VBE participant intends to achieve its value-based purpose). In the context of patient engagement tools and supports, the VBE must connect the provision of tools and supports to the goal of furthering value-based care that underlies this rulemaking. We emphasize that we perceive the administrative steps required to establish a VBE as relatively minimal, and they should not pose a significant burden on providers and others that desire to furnish protected tools and supports. We also note that solo practitioners are not foreclosed from protection under this safe harbor. A solo practitioner could partner with another entity or individual—without changing the membership of the practitioner's own practice—to form a VBE. As a VBE participant, the solo practitioner would then be eligible to offer protected tools and supports to patients, provided the other conditions of the safe harbor are satisfied.

Comment: Several commenters urged OIG to extend safe harbor protection to providers in rural or underserved areas even if they are not VBE participants. According to commenters, these practices may not have sufficient patient populations or resources to create or participate in a VBE.

Response: We do not believe the modest administrative steps required to establish a VBE will be a barrier to most entities—including providers serving rural or underserved patients—that are seeking to offer tools and supports to beneficiaries. Moreover, we believe that requiring entities to fulfill certain VBE-related requirements will help ground any offer or provision of patient engagement tools and supports in the value-based objectives central to this rule, namely the coordination and management of patient care. A VBE does not require a target patient population to be a particular size, and in any event a small practice or a provider in a rural or underserved community may partner with larger providers or other entities with more resources to form VBEs. Accordingly, the final rule does not offer providers in rural or underserved areas an exception to the safe harbor's condition that requires that the individual or entity offering or furnishing protected tools and supports be a VBE participant.

Comment: Commenters recommended that tools and supports furnished or funded by various specific types of entities should be eligible for protection under this safe harbor. In particular, commenters recommended that pharmaceutical manufacturers; manufacturers, distributors, and suppliers of DMEPOS; and laboratories—all of which were ineligible for VBE participation per the definition of ''VBE participant'' in the OIG Proposed Rule—should be eligible to furnish or fund protected tools and supports under this safe harbor. Commenters also noted that pharmaceutical manufacturers; manufacturers, distributors, and suppliers of DMEPOS; and laboratories increasingly are diversified entities that include corporate affiliates and business units that provide a wide range of items and services, including health technologies, care coordination and clinical management, and other offerings and services. Commenters also urged that pharmacists, pharmacies, pharmacy benefit managers, dialysis facilities, and health technology companies should be eligible for protection under the patient engagement and support safe harbor.

Response: Under the final rule, tools and supports furnished or funded by manufacturers, distributors, and wholesalers of pharmaceuticals; individuals and entities that sell or rent DMEPOS; pharmacy benefit managers; laboratory companies; pharmacies that primarily compound drugs or primarily dispense compounded drugs; medical device distributors and wholesalers; and physician-owned medical device companies are not eligible for protection under the patient engagement and support safe harbor. Based on our longstanding enforcement and oversight experience, there is a risk that these entities could misuse this safe harbor to offer remuneration to beneficiaries as a means to market their products and services rather than advancing the goal of improving the coordination and management of patient care. For the same reasons, medical device manufacturers are not eligible for protection under this safe harbor except to the extent the tools or supports provided are digital health technology.

Similar to the care coordination arrangements safe harbor, we have taken a tailored, risk-based approach to address protection for the provision of digital health technology to patients. Among the entities that are otherwise ineligible for this safe harbor, we have identified manufacturers of devices or medical supplies as an entity type that should, to advance the policy goals of this rulemaking, have a limited pathway for protection when they provide digital health technologies as defined in this rule. Under the final rule, manufacturers of devices or medical supplies as defined in paragraph 1001.952(ee)(14) are eligible for protection under the patient engagement and support safe harbor, but only to the extent that the tools and supports they provide to patients meet the definition of digital health technology, as also defined in paragraph 1001.952(ee)(14). All VBE participants that are eligible to use this safe harbor may provide patients with digital health technology. Eligible VBE participants, other than a manufacturer of a device or medical supply, are not limited to digital heath technology as defined at paragraph 1001.952(ee)(14) as long as all safe harbor conditions are met.

Under the final care coordination arrangements safe harbor, DMEPOS companies (*i.e.,* entities or individuals that sell or rent DMEPOS (other than a pharmacy, a manufacturer of a device or medical supply, or a physician,

[56] 84 FR 55722 (Oct. 17, 2019).

provider, or other entity that primarily furnishes services)) are also eligible for the limited technology participant pathway. However, for the patient engagement and support safe harbor, we are finalizing our proposal to make companies that sell or rent DMEPOS ineligible for the safe harbor without exception. We make this distinction based on the different roles and risks associated with entities and individuals that sell or rent DMEPOS when they interact directly with patients. Our enforcement experience reveals persistent and troubling fraud and abuse in sectors of the DMEPOS industry, including inducements paid to beneficiaries to order medically unnecessary products or to disclose their Medicare beneficiary identifier or other personal information. Entities and individuals that sell or rent DMEPOS have more pervasive and personal relationships with individual patients and sell more products directly to patients than manufacturers of medical devices and supplies. This restriction does not mean that patients cannot receive digital tools and supports related to DMEPOS under the safe harbor, but they cannot be provided or funded by entities and individuals that sell or rent DMEPOS. Arrangements between entities and individuals that sell or rent DMEPOS and patients would be subject to a case-by-case analysis for compliance with the Federal anti-kickback statute.

Consistent with the discussion in section III.B.2.e.ii, the final rule lists ''an entity or individual that sells or rents'' DMEPOS as ineligible for safe harbor protection unless the entity or individual is a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services. This approach focuses on the nature of the entity's business rather than relying on unrelated definitions of ''distributor'' or ''supplier.'' As explained in section III.B.2.e.ii, carving out pharmacies, providers, and other entities that primarily furnish services will ensure that these entities—which are likely to be at the front lines of care coordination—remain eligible for safe harbor protection.

For purposes of the patient engagement and support safe harbor, a manufacturer of a device or medical supply is eligible for protection, as provided in paragraph 1001.952(hh)(1)(vi), even if it rents or sells DMEPOS. The multiple business lines analysis would not be needed. The definition for DMEPOS companies at paragraph 1001.952(hh)(1)(vi) is different from the definition of DMEPOS companies for the care coordination arrangements safe harbor to effectuate and clarify the policy goal that the patient engagement and support safe harbor protect digital technology provided by medical device and supply manufacturers.

Regarding commenters' concern about the potential impact of the safe harbor's entity carve-outs on diversified entities that include corporate affiliates and business units that provide a wide range of items and services, we reiterate the discussion in section III.B.2.e.v above regarding entities with multiple lines of business.

Among other specific entity types addressed by commenters, we note that the only entities not eligible to provide protected remuneration under this safe harbor are those entities listed in paragraph 1001.952(hh)(1). Accordingly, many of the entities mentioned by commenters including many pharmacists and pharmacies and dialysis facilities could furnish protected tools and supports, provided all conditions of the safe harbor are satisfied. Pharmacy benefit managers are not eligible to furnish protected tools and supports under this safe harbor for the reasons set forth at section III.B.2.e. Health technology companies are eligible to be VBE Participants and furnish protected tools and supports. If the health technology company is a manufacturer of a device or medical supply, then it may only furnish protected tools and supports in the form of digital health technology. If the health technology company is an entity or individual that sells or rents DMEPOS covered by a Federal health care program (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services) or any other type of ineligible entity, it may not use this safe harbor.

As explained in more detail in section III.B.2.e.ii.f, pharmacies that primarily compound drugs or primarily dispense compounded drugs are ineligible for protection under the patient engagement and support safe harbor. We have significant concerns about fraud and abuse risks based on enforcement and oversight experience involving compounding pharmacies. Although pharmacies that primarily compound drugs or primarily dispense compounded drugs are ineligible for safe harbor protection, we believe most community pharmacies would remain eligible. As explained in section III.B.2.e.iv, we believe that many community and retail pharmacies have the potential to be VBE participants and further the coordination and management of patient care, including through the provision of patient engagement tools and supports. Accordingly, pharmacies (other than compounding pharmacies) are fully eligible for protection under this safe harbor.

Comment: Some commenters objected to categorically limiting protection based on entity type altogether, urging OIG to focus on program integrity safeguards that could prohibit inappropriate behavior rather than carving out categories of entities from protection. A commenter suggested that, to the extent OIG retains its categorical approach in the final rule, it should clarify that parties will not be ineligible for safe harbor protection on the basis of corporate affiliates, shared ownership, or separate business units.

Response: As noted in our response to the prior comment, the entities listed in paragraph 1001.952(hh)(1) may not furnish protected tools and supports under this safe harbor because of the risk that tools and supports from these entities could improperly influence patients or physicians. The final rule does not explicitly prohibit an entity that is a corporate affiliate or under shared ownership with an ineligible entity from offering protected tools and supports. For entities with multiple business lines, this preamble at section III.B.2.e.v describes the analysis to determine whether such an entity would be considered one of the ineligible entity types under this safe harbor. Notably, corporate affiliation—whether by majority ownership, common ownership, or another structure—has no bearing on eligibility for safe harbor protection under the patient engagement and support safe harbor.

Comment: Several commenters recommended that OIG structure the patient engagement and support safe harbor to protect tools and supports offered by Indian health programs.

Response: We are mindful of the important work done by Indian health programs and the critical needs of their patient populations for improved coordination and delivery of care. Indian health care providers that become VBE participants are eligible to use this safe harbor to provide tools and supports to beneficiaries. We did not propose and have not structured a specific safe harbor for Indian health programs. Providers interested in patient engagement programs can also use the local transportation safe harbor. It is important to note that arrangements that do not fit in a safe harbor are not necessarily unlawful, and the OIG advisory opinion process remains

available for providers seeking a legal opinion regarding an existing or proposed arrangement.

Comment: In response to our solicitation of comments in the OIG Proposed Rule regarding a potential condition that safe harbor protection is only available to entities that assume downside financial risk, several commenters urged OIG not to adopt such a financial risk assumption requirement. One commenter opined that there is no logical connection between a provider's financial risk and the benefits of patient engagement. Another commenter noted that adding a financial risk requirement could limit application of this safe harbor to large practices and health systems, positing that small, rural, and underserved practices are unable to take on financial risk and therefore would not be able to provide tools and supports protected by the safe harbor should it include a requirement that protected offerors assume downside financial risk. A commenter noted that for a VBE with downside financial risk there is no incentive to provide an item, tool, support, or service that is not related to treating or preventing a disease or injury among a target patient population. As such, inherently, the VBE participant must believe the tool or support will provide a medical or health benefit to the patient to whom it is being given. Another commenter with experience as a risk-bearing ACO entity supported limiting this safe harbor to VBEs engaged in risk-bearing arrangements, citing a learning curve in the appropriate use of tools and supports, and highlighting that the assumption of downside financial risk may offset some of the traditional fraud and abuse concerns, such as overutilization.

Response: We agree with commenters and believe that various providers and other entities—including those who have not assumed downside financial risk—could engage in beneficial patient engagement and support. Consequently, in an attempt to promote flexibility and innovation related to patient engagement and support, the safe harbor as finalized in this rule does not contain a financial risk requirement.

c. Limitations on Recipients

Summary of OIG Proposed Rule: The proposed safe harbor protected only tools and supports furnished by a VBE participant to a patient within a defined ''target patient population,'' as that term is defined at proposed paragraph 1001.952(ee)(12)(ii), and without regard to payor type. We solicited comments on whether to broaden the category of patients who can receive protected tools and supports under this safe harbor to include, for example, any patient, so long as the tools and supports predominantly address needs of the target patient population and the tools and supports have a direct connection to the coordination and management of care for the patient.[57]

Summary of Final Rule: We finalize, with modification, our proposal to limit safe harbor protection to tools and supports provided to patients in a target patient population. The final safe harbor clarifies our intent that, to qualify for safe harbor protection, a tool or support must be furnished by a VBE participant to a patient in the target patient population of a value-based arrangement to which the VBE participant is a party. This language ensures that the remuneration is linked to the target patient population relevant to the VBE to which the VBE participant is a party. It further ensures that the remuneration has a direct connection to the coordination and management of care of the relevant target patient population, as set forth in the condition at paragraph 1001.952(hh)(3)(ii).

Comment: Several commenters appreciated that we proposed protection for patient engagement tools and supports offered to a target patient population, notwithstanding payor type, and agreed as a general matter that the provision of protected tools and supports should be limited to the target patient population.

Response: We have finalized the condition, as proposed. The safe harbor only protects remuneration provided to a patient in a target patient population.

Comment: Some commenters suggested that this safe harbor not incorporate the definition of ''target patient population'' proposed at paragraph 1001.952(ee)(12)(ii), or that this safe harbor protect tools and supports given to certain patients outside the target patient population. Other commenters proposed alternative ''target patient population'' definitions or exceptions for rural and underserved communities outside of the VBE construct, as well as exceptions designed to address social determinants of health. Commenters also asked us to finalize a broad category of protected recipients without any defined parameters, such as limiting the scope of protected recipients to patients with a specific disease state or certain chronic conditions. Several commenters highlighted problems with and sought clarity regarding a VBE participant's inability to retrospectively or prospectively identify or assign patients to the target patient population, and whether a precise population was required to satisfy the definition of ''target patient population'' for purposes of this safe harbor.

Response: The final safe harbor retains the conditions that a protected tool or support must be provided to a patient in the target patient population and must have a direct connection to the coordination and management of care of the target patient population. We believe that requiring a VBE participant to specify a target patient population prior to offering patient engagement tools and supports will help tie the tools and supports to the underlying value-based purposes of the VBE and will necessitate careful consideration of the objective characteristics of the patient population that likely will benefit from any offered tools and supports. We also believe that a connection to an objectively defined target patient population decreases the risk that valuable remuneration will be offered to patients as an inducement to seek care. We have incorporated the definition of ''target patient population'' as finalized at paragraph 1001.952(ee)(14)(v) for the sake of consistency and because VBE participants will have familiarity with the defined term through the creation of a VBE.

As noted in the summary above, we also are finalizing the proposed requirement that only tools and supports furnished by VBE participants are eligible for protection under this safe harbor. This provision does not impose additional burdens on VBE participants. Establishing a VBE requires articulating a value-based purpose and defining a target patient population, which significantly contributes to meeting this condition. The requirement that a patient engagement tool or support be furnished by a VBE participant to a patient in a target patient population does not include any exceptions for patients in rural or underserved areas, or for remuneration intended to address social determinants of health. We emphasize, however, that VBE participants have considerable flexibility in determining how to define a target patient population, as long as the population is selected using legitimate and verifiable criteria that are set out in writing and further the VBE's value-based purpose. In addition, VBE participants could establish multiple target patient populations for the purposes of furnishing tools and supports to be protected by this safe harbor as long as all safe harbor conditions are satisfied.

Comment: Many commenters supported the alternative language for

[57] 84 FR 55723 (Oct. 17, 2019).

which we solicited comments, which would have protected tools and supports furnished to any patient, as long as the tools and supports predominantly address the needs of the target patient population, and the tools and supports have a direct connection to the coordination and management of care for the patient, noting, for example, that it can be challenging to make accurate prospective predictions of which patients are aligned with a target patient population at any given time.

Response: In this final rule, we decline to protect remuneration furnished to patients outside a specified target patient population. Limiting protected tools and supports only to patients within the target patient population will help to ensure the tools and supports have a nexus to the VBE's underlying value-based purpose in a way that might be more attenuated under our alternative proposal.

Comment: Some commenters recommended that the safe harbor protect the provision of tools or supports for patients whose conditions or circumstances are similar to those of the target patient population, highlighting the risk of penalties associated with providing tools and supports to patients who could benefit from them despite falling outside of the target patient population.

Response: The final safe harbor requires VBE participants seeking protection under the patient engagement and support safe harbor to define the scope of the applicable target patient population to include patients likely to benefit from the relevant tools and supports. As discussed above in more detail in section III.B.2.c, the selection criteria—not the individual patients—must be identified in advance. Parties may modify their target patient population selection criteria prospectively by amending their existing value-based arrangement. VBE participants can retroactively attribute patients to the target patient population without amending the value-based arrangement if such patients meet the selection criteria established prior to the commencement of the value-based arrangement.

d. Furnished Directly to the Patient

Summary of OIG Proposed Rule: We proposed to include a condition at proposed paragraph 1001.952(hh)(1) that the tool or support must be furnished directly to the patient by a VBE participant. We solicited comments on arrangements through which a VBE participant might order or arrange for the delivery of a tool or support from an independent third party. We also sought comment on whether to expressly permit a VBE participant to furnish the tool or support through someone acting on the VBE participant's behalf and under the VBE's direction, such as a physician practice that is a VBE participant providing a tool or support through an individual member of the practice or a nurse employed by the practice. We also solicited comments regarding whether to require patient notice if third parties are involved in the furnishing of the tool or support.

Summary of Final Rule: We are finalizing, with modification, this condition at paragraph 1001.952(hh)(2). The final rule extends safe harbor protection to a VBE participant that provides patient engagement tools or supports through a third party that qualifies as an ''eligible agent,'' as defined in paragraph 1001.952(hh)(9).

Comment: Most commenters did not support the condition requiring that tools or supports be furnished directly to the patient by the VBE participant, for several reasons. For example, commenters asserted that, depending on the size or sophistication of the VBE participant's practice, the VBE participant may outsource the furnishing of the tool or support, or otherwise not be present at the time it is furnished. Others suggested that a partner or an agent of a VBE participant, such as a vendor, contractor, or employee of the participant, should also be permitted to furnish the patient engagement tools or supports at the direction of the VBE participant, noting that for entities and individuals furnishing tools and supports, outsourcing the provision of such tools and supports to independent third parties is a common practice. Other commenters recommended protection of tools and supports provided by nontraditional or nonclinical (but health-related) third parties that address social determinants of health or transportation needs. For example, a health system commenter indicated that it contracts with vendors to provide digital devices and tools to patients. Another commenter also provided an illustrative example, explaining that to furnish a patient with a ''grab bar'' at home, it would purchase a grab bar through an online retailer and then contract with a local hardware vendor to install the grab bar. Another commenter recommended safe harbor protection for the provision of tools and supports through which the third party is under the control and oversight of the VBE participant and is otherwise eligible to participate in a VBE (as proposed in the OIG Proposed Rule).

Response: We agree that the safe harbor should protect the provision of tools and supports through a person or entity acting on behalf of the VBE participant and under the VBE participant's direction, but only if certain conditions are met. Requiring that the tool or support be furnished directly to the patient by the VBE participant prevents entities that are ineligible to participate in a VBE from directly or indirectly furnishing tools or supports to patients. Also, as we explained in the OIG Proposed Rule, the requirement would help patients understand who is furnishing the tool or support and why. Notwithstanding, we have finalized a provision at paragraph 1001.952(hh)(2) that extends protection to tools and supports furnished through a VBE participant's ''eligible agent,'' assuming the other conditions of the safe harbor are met. For purposes of this paragraph, ''eligible agent'' means any person or entity that is not identified in paragraph 1001.952(hh)(1)(i)–(viii) as ineligible to furnish protected tools and supports. Thus, the eligible agent must be an individual or entity that could furnish protected tools and supports under paragraph 1001.952(hh)—even though the eligible agent does not itself need to become a VBE participant. The VBE participant's eligible agent could be, for example, employees and contractors of a practice when the VBE participant is the practice itself, or other third parties such as technology vendors or retailers. This condition also means that an entity precluded from furnishing or funding protected tools and supports under paragraph 1001.952(hh)(1) cannot be an eligible agent of a VBE participant for purposes of furnishing a protected patient engagement tool or support. Furthermore, this safe harbor does not protect any remuneration that flows through or is furnished by a third party that is not an eligible agent.

Comment: Some commenters recommended that a tool or support be eligible for safe harbor protection if it is furnished to a caregiver or family member of a patient in the target patient population.

Response: We agree that a tool or support should be eligible for safe harbor protection if it is furnished to a caregiver or family member of a patient in the target population, as long as the tool or support satisfies all conditions of the safe harbor conditions. As we stated in the OIG Proposed Rule, a tool or support would not be considered ''diverted'' if furnished to the patient indirectly through the patient's caregivers or family members, or through another individual acting on behalf of the patient. We provided

examples of such scenarios, including one in which a patient is unable to care for himself or herself and another person has legal authority or the patient's consent to do so, such as when a parent caring for a minor child with asthma accepts and installs an air purifier on behalf of the child.[58] Although we included this discussion in the context of a proposed condition to mitigate potential diversion of patient engagement tools and supports—which is not being finalized in this rule—we nevertheless believe the discussion is applicable to the ''furnished directly'' condition at paragraph 1001.952(hh)(2). Accordingly, intervening caregivers and family members or others acting on behalf of the patient may facilitate the provision of the tool or support without the remuneration running afoul of the ''furnished directly'' requirement if all other conditions of the safe harbor are satisfied.

Comment: Some commenters suggested that when a third party is providing the tool or support, the patient should be notified in writing or otherwise about the sponsor and other details about the vendor and the purpose of the tool or support. Other commenters objected to any additional notification requirements as burdensome to the provider and the patient.

Response: We appreciate the commenters' suggestion but decline to impose such a notification requirement. The safe harbor only protects the provision of tools and supports that are recommended by a patient's health care professional, and many of the enumerated goals in the safe harbor also require the involvement of the patient's licensed health care professional. Based on these conditions, we believe beneficiaries are unlikely to receive tools or supports that otherwise meet the conditions of the safe harbor without an awareness of the source and purpose of those items or services. Furthermore, lack of awareness of the source and purpose also may diminish the likelihood for improved patient engagement. To best promote patient engagement and ensure the benefits of any tools and supports are realized, VBE participants have an incentive to clearly communicate about the tools and supports they provide without a formal patient notification requirement.

e. Funding Limitations

Summary of OIG Proposed Rule: In proposed paragraph 1001.952(hh)(2), we proposed to prohibit any third-party entity or individual outside of the VBE from financing or otherwise contributing to the provision of patient engagement tools or supports. In the OIG Proposed Rule, this condition would have prevented entities not eligible to become VBE participants from circumventing that limitation and seeking protection for tools and supports they furnished to patients under the patient engagement and support safe harbor.

Summary of Final Rule: We are finalizing, with modifications, this condition at paragraph 1001.952(hh)(4). Specifically, the final regulation text states that the patient engagement tool or support must not be funded or contributed by a VBE participant that is not a party to the applicable value-based arrangement or by an entity listed at paragraph 1001.952(hh)(1)(i) through (viii). The modifications have been made to ensure that the specified entities ineligible for protection under this safe harbor at paragraph 1001.951(hh)(1) are not able to circumvent that restriction by indirectly funding or contributing to tools and support protected under this safe harbor. This condition also clarifies our intent that the VBE participant must be a party to the ''applicable value-based arrangement.'' In other words, the patient receiving the tool or support must be a member of the target patient population of a VBA to which the VBE participant is a party. This also ensures that the remuneration has a direct connection to the coordination and management of care of the target patient population of the applicable VBA to which the VBE participant is a party. The condition at paragraph 1001.952(hh)(4) effectuates our proposed policy to bar safe harbor protection for tools and supports funded by entities that, under the proposed rule, could not have been in a VBE (see section III.B.2.e.ii for discussion of these entities). The safe harbor does not protect any patient engagement tools and supports funded by or involving contributions from entities identified at paragraph 1001.952(hh)(1)(i) through (viii).

Comment: Several commenters found this condition unduly restrictive, citing potential challenges with meeting this condition when delegating the provision of tools and supports or sharing a care coordinator with someone outside of the VBE. Another commenter stated that entities explicitly ineligible for participation in a VBE under the OIG Proposed Rule's definition of ''VBE participant'' play a vital role in supporting the care of patients, and without funding from such entities, hospitals and payors would be limited regarding what types of patient engagement tools and supports they could provide.

Response: We are finalizing this condition with modifications. This condition is an important safeguard that prevents entities ineligible for safe harbor protection from circumventing the conditions of the safe harbor by doing indirectly what they cannot do directly. Regarding commenters' concerns about the impact of this condition on the ability to delegate the provision of tools or supports, we emphasize that, as discussed in the prior section of this preamble, VBE participants may provide tools and supports via an eligible agent, which can be any third party as long as the third party is not otherwise ineligible to furnish protected tools and supports under this safe harbor.

Comment: A commenter supported this condition, noting that outside funding or contributions pose a risk of inappropriate steering to specific suppliers of products or services. Other commenters appreciated the purpose of this limitation but asked OIG to allow for certain donations from foundations or charities to a VBE, together with a safeguard prohibiting the donating third party from having direction or control over how the funds are spent. Another commenter stated that other types of entities such as construction companies may offer to modify homes with ramps and wider doors, among other things, without charge, and that this condition could prevent protection for such donations.

Response: We appreciate that many entities would like to fund or otherwise contribute to protected patient engagement tools and supports provided by a VBE participant, including through charitable or otherwise arm's-length donations made to a VBE. Our goal in implementing the funding and contribution limitations is to ensure that entities that may not furnish protected tools and supports directly are unable to indirectly provide or fund protected tools and supports. We believe that limiting the types of entities that may fund protected tools and supports is an important safeguard against circumvention schemes, including potential arrangements involving foundations or charities. Without the funding and contribution limitations, it is possible that entities ineligible to provide tools and supports could indirectly fund such items or services through a foundation, charity, or other entity, which could make it difficult to determine the ultimate source of funding. We believe the final funding and contribution limitations described

[58] 84 FR 55728 (Oct. 17, 2019).

here provide sufficient flexibility for VBE participants to provide protected tools and supports while safeguarding against the heightened risk of fraud and abuse related to tools and supports furnished to patients by the types of entities that are ineligible for safe harbor protection.

Nothing in this condition would prevent a charity or foundation from providing tools and supports directly to patients, assuming such an arrangement complies with the Federal anti-kickback statute or Beneficiary Inducements CMP, if either statute is implicated. If the charity or foundation is not funded by health care entities, the arrangement might not implicate the statutes. Further, nothing in this safe harbor would prevent construction companies from modifying homes with ramps, widening doors, or providing other construction services for free to patients, provided those arrangements comply with the statute. Free services offered to a patient directly by a construction company that does not provide Federally reimbursable items or services or make referrals for them would not implicate the statutes, and therefore, safe harbor protection would not be needed. However, such free services offered through an intermediary that provides federally reimbursable items and services, such as a hospital, would need to be evaluated on a case-by-case basis under the statute; the arrangement between the construction company and hospital would not implicate the statute, but the arrangement between the hospital and patient might.

f. Nature of the Remuneration

Commenters provided numerous suggestions regarding specific types of remuneration potentially protected under this safe harbor. In the sections below, we respond to such comments and provide examples of potentially protected types of remuneration, but we note that the examples or categories of items, goods, and services included here are neither exhaustive nor presumptively protected under this safe harbor. Specifically, we remind stakeholders that all conditions of the safe harbor must be squarely satisfied for the tools and supports to be protected by the safe harbor.

i. In-Kind Remuneration

Summary of OIG Proposed Rule: At proposed paragraph 1001.952(hh)(3)(i), we proposed to protect any in-kind preventive item, good, or service, or an in-kind item, good, or service such as health-related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health.

Summary of Final Rule: We are finalizing, with modifications, the provision at paragraph 1001.952(hh)(3)(i). The final rule protects patient engagement tools and supports that are in-kind items, goods, and services provided they meet all applicable safe harbor conditions. We are not finalizing the regulatory text at proposed paragraph 1001.952(hh)(3)(i) that provided specific examples of protected in-kind items, goods, or services (*i.e.,* health-related technology, patient health-related monitoring tools and services, supports and services designed to identify and address social determinants of health). As finalized by this rule, paragraph 1001.952(hh)(3)(i) specifies that protection is offered only for in-kind items, goods, or services, without specifying categories of items, goods, or services. We believe including nonexhaustive categories in regulatory text was not necessary or helpful to explain the meaning of an ''in-kind item, good, or service.'' These changes are intended to ensure the final rule does not inadvertently preclude types or categories of tools or supports that could receive protection under the safe harbor. Provided that all safe harbor requirements are satisfied, the final rule protects a broad range of tools and supports that may include, among others, health-related technology, patient health-related monitoring tools and services, and supports and services designed to identify and address a patient's social determinants of health. We have modified and reorganized the regulatory text to better effectuate this policy.

Based on public comments, we confirm that preventive items, goods, or services can be protected under this safe harbor. However, we are not finalizing the proposed regulatory text at paragraph 1001.952(hh)(3)(i) regarding preventive care. To make clear that preventive items, goods, or services can fit in the safe harbor, we have amended the goal of ''management of a disease or condition'' to read ''prevention or management of a disease or condition'' at paragraph 1001.952(hh)(3)(vi)(D).

Comment: A number of commenters supported our overall approach to identify categories of protected in-kind remuneration instead of endeavoring to provide a comprehensive list of tools and supports eligible for safe harbor protection and believed that the categories proposed are—and should remain—sufficiently flexible to encompass a range of tools and supports across various care settings. Commenters stated that VBEs should have flexibility to determine the most appropriate tools and supports to provide as a part of the arrangements and recommended against OIG specifying a list of tools and supports that could, ultimately, stifle innovation, particularly with respect to tools and supports designed to address social determinants of health. Alternatively, some commenters encouraged us to provide greater specificity and more examples of protected patient engagement tools and supports based on comments received in response to the OIG Proposed Rule. For example, a commenter urged OIG to provide as many examples as possible of the tools and supports that would and would not be protected by this safe harbor in the preamble to the final rule. Others requested some examples but urged us to clarify that any examples are illustrative, not exhaustive.

A commenter supported protection for tools and supports that impact positive behavioral change, such as receiving an annual wellness visit, participating in a smoking cessation program, or seeking care from a lower cost provider (*e.g.,* receiving imaging services in a freestanding setting as opposed to a hospital outpatient department). The commenter also supported addressing a barrier to adhering to a care plan, such as providing cooking classes to facilitate the preparation of healthy meals, providing condition-specific groceries, or providing condition-specific technology (*e.g.,* electronic scales, internet service to facilitate data collection, or both). Another commenter listed examples of additional dialysis-related tools and supports that should be covered.

Response: Rather than listing specific examples of tools and supports potentially eligible for protection under this safe harbor, the final safe harbor contains a list of goals at paragraph 1001.952(hh)(3)(vi), at least one of which a tool or support must advance in order to qualify for safe harbor protection. We believe this provides substantial flexibility for VBE participants to offer a wide range of tools and supports.

As noted above, we have omitted the examples of remuneration listed in proposed paragraph 1001.952.(hh)(3)(i). With respect to tools and supports designed to address a patient's social determinants of health, such remuneration is protected if it meets one of the final safe harbor's enumerated goals listed at paragraph 1001.952(hh)(3)(vi). This change is intended to ensure the final rule is agnostic about the specific types or

categories of tools and supports protected by this safe harbor. As a result, health-related technology and patient health-related monitoring tools and services are eligible for safe harbor protection if they meet the other conditions of the safe harbor, including at least one of the goals at paragraph 1001.952(hh)(3)(vi).

We have provided some examples of categories and specific tools and supports in the discussion below at section III.B.6.f.iv related to social determinants of health, as well as general descriptions of certain health technologies potentially protected by this safe harbor. We also agree with commenters who suggested that any examples provided in this final rule's preamble should be illustrative rather than exhaustive, to provide for flexibility and innovation in the provision of patient engagement tools and supports. We intend for the safe harbor to protect a range of in-kind remuneration and agree that many of the tools and supports described by the commenters may satisfy the safe harbor if all other conditions of the safe harbor are met.

Comment: A commenter stated that the proposed safe harbor is too narrow to truly drive patient engagement because, although it protects the provision of tools and supports to patients, it does not protect efforts to encourage the utilization of those tools or otherwise protect efforts to incentivize care adherence.

Response: We disagree that the safe harbor lacks sufficient regulatory flexibility for the provision of tools and supports that promote patient engagement. In response to the suggestion that the safe harbor should protect efforts to encourage the utilization of protected tools and supports, we note that nothing in the safe harbor would limit the ability of VBE participants to educate patients about available tools and supports as long as the VBE participant does not use the patient engagement tools or supports to market other reimbursable items or services, or for patient recruitment purposes, as prohibited at paragraph 1001.952(hh)(6).

In response to the suggestion that the safe harbor should protect efforts to incentivize care adherence, we note that a VBE participant must ensure that the tool or support advances an enumerated goal at paragraph 1001.952(hh)(3)(vi), several of which involve patient adherence. For example, the safe harbor protects tools and supports that advance goals for adherence to a treatment regimen, adherence to a drug regimen, and adherence to a followup care plan if all other conditions are met. In addition, we think that the conditions requiring a licensed health care professional to recommend the tool or support and requiring that the tool or support be directly connected to the coordination and management of care require the offeror to evaluate whether the tool or support will advance the enumerated goals listed in the safe harbor.

Comment: A commenter requested OIG clarify its interpretation of the phrase ''preventive care item or service'' for the purposes of this safe harbor to ensure that the definition remains flexible enough to encompass rapidly advancing technology. Another commenter requested that we add ''primary and secondary prevention'' to the regulatory text of this safe harbor to clarify that various forms of preventive efforts are protected by the safe harbor. Another commenter requested that we add ''tertiary'' prevention. Commenters generally supported OIG's proposal to defer to VBE participants or physicians in determining: (i) What constitutes a preventive item or service for the purposes of this safe harbor; and (ii) the appropriate tools and supports to address such preventive care, asserting that physicians are in the best position to assess whether a particular item or service is preventive.

Response: Tools and supports in furtherance of preventive care and services can be protected under this safe harbor if the other conditions are satisfied. The final safe harbor regulation does not identify a specific category of remuneration for preventive care items, goods, or services. Instead, preventive items, goods, and services could be protected under the safe harbor's general protection of in-kind items, goods, or services that satisfy the conditions of the safe harbor, including advancing one of the safe harbor's enumerated goals. For example, a preventive item, good, or service could advance the goal of ''prevention or management of a disease or condition'' at paragraph 1001.952(hh)(3)(vi)(D).

ii. Cash, Cash Equivalents, and Gift Cards

Summary of OIG Proposed Rule: We proposed at proposed paragraph 1001.952(hh)(3)(iii) to exclude protection for remuneration in the form of cash, cash equivalents, and gift cards, and we sought additional comments on whether the safe harbor should protect those forms of remuneration.

Summary of Final Rule: We are finalizing, with modification, the proposed condition at paragraph 1001.952(hh)(3)(iii). The final regulatory text does not reference gift cards because some gift cards would be considered in-kind remuneration eligible for safe harbor protection. Cash, cash equivalents, and most gift cards are excluded in the final rule because the safe harbor is limited to in-kind remuneration.

Comment: Several commenters echoed the concerns we raised in the OIG Proposed Rule regarding the risks of protecting cash, cash equivalents, and gift cards under the safe harbor, urging us to limit safe harbor protection to in-kind remuneration to reduce the risk of inappropriate patient steering or coercion.

Response: We agree with these comments, and we believe restricting protection to in-kind remuneration in the final rule reflects OIG's longstanding concern about the fraud and abuse risks inherent to providing cash, cash equivalents, or gift cards to beneficiaries.

Comment: A number of commenters urged OIG to protect gift cards under this safe harbor. In particular, several commenters suggested that we clarify that a voucher provided through a debit card-like mechanism that could be used to acquire tools or supports, such as food or transportation, would be considered ''in-kind'' under the safe harbor. Another commenter urged OIG to protect the provision of gift cards but suggested that prepaid debit cards should be excluded from protection, similar to existing OIG guidance regarding cash and cash equivalents.

A commenter recommended protecting gift cards that may be redeemed only at certain stores for certain purposes consistent with OIG's previous guidance on cash and cash equivalents, as long as they are not advertised or otherwise included in prospective marketing or promotional efforts, and earned via active, verifiable participation in core elements of a beneficiary's treatment plan.

A commenter noted that gift cards provide sufficient flexibility with less risk than cash, noting that a gift card may be exchanged for cash, but typically at a reduced value.

Response: As we stated in the preamble to the OIG Proposed Rule, we would consider a voucher for a particular tool or support (*e.g.,* a meal voucher or a voucher for a taxi) to satisfy the safe harbor's in-kind requirement. However, consistent with our treatment of these issues in prior regulations,[59] we consider debit cards, rebate checks, and most gift cards to be cash equivalents and not a protected

[59] 81 FR 88393 (Dec. 7, 2016).

form of in-kind remuneration under this safe harbor.

We are not, however, departing from OIG's existing guidance regarding limited-use gift cards.[60] Gift cards that can be redeemed only for certain categories of items (such as fuel-only gift cards redeemable at gas stations) could meet the in-kind requirement under this safe harbor. Gift cards meet the in-kind requirement only if their potential use is limited to certain categories of items or services that meet the conditions of the safe harbor. For instance, a gift card for a service that delivers the ingredients necessary for a healthy meal would meet the in-kind requirement and could be protected if the other conditions of the safe harbor are satisfied. Gift cards offered by large retailers or online vendors that sell a wide variety of items (*e.g.,* big-box stores) could easily be diverted from their intended purpose or converted to cash; we would consider such gift cards to be cash equivalents and therefore not eligible for protection under this safe harbor.

Comment: A commenter posited that when gift cards are furnished to patients within the VBE context, the financial model of VBEs serves as an inherent safeguard against unnecessary and excessive utilization. The commenter asserted that when a VBE is financially at risk for improving outcomes, the VBE likely would not furnish gift cards to patients to drive unwarranted utilization and would be financially incentivized to encourage only beneficial utilization that improves health and helps manage the total cost of care.

Response: Although we recognize that VBEs assuming downside financial risk may have incentives to avoid offering tools and supports to beneficiaries that could drive medically unnecessary utilization, we are not, as discussed above, requiring VBE participants under this safe harbor to assume some degree of financial risk. We believe that some of the risks associated with fee-for-service payment systems—such as overutilization—may continue to exist in VBEs where VBE participants continue to be paid on a fee-for-service basis. Therefore, there is a risk that VBEs would furnish gift cards to patients to drive inappropriate utilization, but such conduct would not be protected by this safe harbor and may implicate the Federal anti-kickback statute.

Comment: Several commenters urged OIG to protect cash, cash equivalents, and gift cards under this safe harbor but to attach additional safe harbor conditions to such means of remuneration. For example, a commenter suggested that cash, cash equivalents, and gift cards should be protected as a reward for taking a particular action, but that remuneration should be provided only after a patient has taken the required action. Another commenter suggested that OIG protect cash, cash equivalents, and gift cards but impose a separate monetary cap that parallels OIG's nominal value guidance. The commenter also urged OIG to consider requiring that any patient eligible to receive a cash or cash-equivalent incentive would need to be an ''established patient'' as defined in the local transportation safe harbor, paragraph 1001.952(bb).

Other safeguards recommended by commenters specific to cash, cash equivalents, and gift cards include: Prohibiting the advertising of rewards; tying incentives to outcomes associated with the prescribed course of treatment; a requirement that incentives cannot be utilized to generate business or otherwise promote the utilization of unnecessary or inappropriate items and services; limiting the use of such incentives to items that promote health and wellness, such as nutritious food, exercise equipment, or health monitoring and tracking devices; and requiring entities to have an evidence-based reason to believe that cash, cash equivalents, or gift cards can increase patient adherence to recommended medical guidance. A commenter suggested that retrospective evaluation and auditing could be used to identify any potentially fraudulent activity relating to cash, cash equivalents, and gift cards.

Response: We appreciate the commenters' suggestions for additional safe harbor conditions specific to the provision of cash, cash equivalents, and gift cards. Based on longstanding program integrity concerns, the final safe harbor only protects in-kind remuneration to include limited types of gift cards as described further above. OIG historically has had significant concerns about providing protection for providers' and other health care stakeholders' offers of cash or cash equivalents to patients, and our oversight experience suggests that cash and cash-equivalent remuneration raises substantial fraud and abuse risks, including the potential for inappropriate utilization of medically unnecessary items and services and improper patient steering. OIG tailored the final safe harbor's safeguards to in-kind tools and supports; therefore, it is not necessary to adopt additional conditions recommended by commenters specific to the provision of cash, cash equivalents, and gift cards.

Comment: Commenters noted that cash and cash equivalents are a useful way to address social determinants of health and noted that cash and cash equivalents could facilitate patient access to transportation, counseling and coaching, meal preparation, existing and emerging self-monitoring health technologies, and other supports that promote independence and positive health outcomes.

Response: We recognize that cash and cash equivalents may be a useful way to address social determinants of health. We remain concerned, however, for the reasons explained above, that cash or cash-equivalent remuneration to Federal health care program beneficiaries presents an elevated risk of fraud and abuse, and we are finalizing our proposal to protect only in-kind remuneration. Parties can structure a wide range of arrangements involving in-kind remuneration to address social determinants of health under the final safe harbor. For example, in lieu of cash, protected tools and supports could include vouchers or limited-use gift cards (*e.g.,* to address transportation access to medical appointments to advance adherence to a followup care plan, a ride share voucher or gas card could be protected, provided all other safe harbor conditions are satisfied). Arrangements involving cash or cash equivalents used to address social determinants of health are not necessarily illegal; they would need to be evaluated under the anti-kickback statute on a case-by-case basis, including the intent of the parties.

Comment: A commenter asserted that expanding the safe harbor to protect gift cards, discount cards, and coupons toward future services would support the viability of smaller independent practices that operate in consolidated markets and are competing against hospitals and health systems.

Response: We appreciate the commenter's concern regarding consolidation and the potential effects of our safe harbors on competition. This final safe harbor protects certain, limited categories of gift cards in accordance with OIG's previous guidance on cash equivalents and limited-use gift cards. We note that discount cards and coupons may qualify as protected in-kind remuneration as long as the other conditions of this safe harbor are satisfied. We do not, however, intend for this safe harbor to protect waivers or reductions in patient cost-sharing obligations, as discussed below. For example, a coupon designed

[60] 81 FR 88393 n. 19 (Dec. 7, 2016).

to cover only a patient's cost-sharing obligation would not be protected by this safe harbor. We also note that to the extent parties wish to have safe harbor protection for any discounts offered to beneficiaries, they would need to comply with the terms of the discount safe harbor at paragraph 1001.952(h) in order to receive safe harbor protection. Finally, to the extent the commenter is referencing gift cards, discount cards, and coupons that would reward patients for seeking care, such arrangements may not satisfy the prohibition on marketing and patient recruitment at paragraph 1001.952(hh)(6).

Comment: A number of commenters offered general support for extending safe harbor protection to cash, cash equivalents, and gift cards provided to patients as rewards or incentives to promote various behaviors, including attending necessary appointments, adherence to a treatment regimen, or participation in a substance abuse treatment or behavioral modification program. Several commenters cited a body of research suggesting that cash incentives can be effective at improving patient engagement and adherence or behavioral modification. For example, a commenter cited behavioral economics research findings that even nominal amounts of cash or cash-equivalent remuneration can produce substantial improvements in overall health outcomes when used as an incentive to motivate patients to lead healthier lifestyles.

Commenters also noted that gift cards may be employed as rewards for healthy patient behaviors and activities in a number of other contexts, including pursuant to certain section 1115 waiver programs, some Medicaid managed care organizations, and programs or initiatives related to Medicaid Incentives for the Prevention of Chronic Diseases.

Response: In the OIG Proposed Rule, we solicited comments on including gift cards when they are provided to patients with certain conditions, such as substance abuse disorders and behavioral health conditions, as part of an evidence-based treatment program for the purpose of effecting behavioral change. We appreciate the responses from commenters and understand that incentives can effectively drive patient adherence to treatment programs, lead patients to follow healthier lifestyles, or effect other behavioral changes.

For example, we recognize that research shows that contingency management interventions are the most effective currently available treatment for stimulant use disorders. Substance use disorder treatment programs utilizing contingency management often involve payments to the patient in the form of the opportunity to earn vouchers, gift cards, or even, in some models, salaries in exchange for desired prosocial behaviors or meeting specified goals. We also understand and acknowledge that there is a growing problem with stimulant (*e.g.,* cocaine and methamphetamine) co-use with opioids. Combatting the opioid epidemic, including ensuring that patients have access to effective treatment programs, has been a top priority for the Administration, the Department, and OIG. In addition, many treatments involving contingency management interventions have been developed over decades by scientists supported by the Federal government through the National Institutes of Health.

After weighing the potential benefits of contingency management and other programs designed to motivate beneficial behavioral change with the potential risks to program integrity—and understanding that many of these programs involve cash and cash-equivalent payments to patients—we are not expanding the patient engagement and support safe harbor to include cash and cash-equivalent payments offered as part of contingency management interventions or other programs to motivate beneficial behavioral changes. This does not mean that all such cash or cash-equivalent payments are unlawful, but they would be subject to case-by-case analysis under the Federal anti-kickback statute and Beneficiary Inducements CMP. In addition, we emphasize—as further discussed below—that in-kind remuneration and certain limited-use gift cards offered as part of contingency management interventions or other programs to motivate beneficial behavioral changes could receive protection under the patient engagement and support safe harbor if all safe harbor conditions are satisfied. Indeed, OIG's final rule offers many opportunities for those treating patients for substance use disorders to improve the coordination and management of patient care through value-based arrangements between providers that band together to improve care, the provision of in-kind incentives to patients to motivate them to meet treatment goals, and broader flexibilities for transportation arrangements under the existing local transportation safe harbor, which would meet an identified need for patients in rural areas seeking treatment. While not all such arrangements implicate the fraud and abuse statutes, arrangements involving community recovery support systems such as clubhouses and peer-to-peer focused support services would have broader access to safe harbor protection under the final rule.

With respect to nominal amounts of cash or cash-equivalent remuneration mentioned by the commenter, we understand that some industry stakeholders believe OIG's guidance permits cash and cash-equivalent incentive payments up to $75. This is a misunderstanding of OIG's guidance. The Conference Committee report accompanying the enactment of the Beneficiary Inducements CMP expressed Congress' intent that inexpensive gifts of nominal value be permitted.[61] OIG has interpreted inexpensive gifts of nominal value to mean in-kind items and services with a retail value of no more than $15 per item or $75 in the aggregate per beneficiary on an annual basis.[62] Gifts that implicate the Beneficiary Inducements CMP that exceed these dollar limits are not prohibited but are analyzed on a case-by-case basis for compliance under the statute. We highlight, however, that this nominal value guidance applies to the value of in-kind items and services, not to the value of incentive payments in the form of cash or cash equivalents. In other words, cash and cash-equivalent payments under $75 would not be covered by this guidance. Moreover, this guidance applies only with respect to the Beneficiary Inducements CMP and not to the Federal anti-kickback statute. Furthermore, we are aware that some industry stakeholders may be under a misimpression that OIG prohibits contingency management program incentives above $75. There is no OIG-imposed $75 limitation on contingency management program incentives. Rather, the Federal anti-kickback statute may constrain the ability of individuals or entities to offer contingency management program incentives of any value to Federal health care program beneficiaries, depending on the facts of the arrangement. Moreover, in-kind incentives above the $75 annual, aggregate limit, and all cash or cash-equivalent incentives regardless of the amount, must be analyzed on the basis

[61] *See* Joint Explanatory Statement of the Committee of Conference, section 231 of HIPAA, Public Law 104–191.

[62] OIG, Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries (Dec. 7, 2016), *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf.*

of their specific facts for compliance with the Beneficiary Inducements CMP.

With respect to contingency management program incentives and other programs that offer incentives to motivate healthy behaviors—whether above or below $75 in value—we offer the following observations. In-kind remuneration in connection with such programs can fit in the patient engagement and support safe harbor if all safe harbor conditions are met (including the $500 annual cap). As further explained in this section, the final safe harbor protects certain limited-use gift cards that advance one or more of the enumerated goals at paragraph 1001.952(hh)(3)(vi) and meet other safe harbor conditions, including that the remuneration must have a direct connection to the coordination and management of care of the target patient population. To the extent that a program involves salary payments to a bona fide employee for services furnished by the employee, the payments might qualify under the existing safe harbor for employees at paragraph 1001.952(i).

If a contingency management incentive that implicates the Federal anti-kickback statute, Beneficiary Inducements CMP, or both does not satisfy an existing safe harbor or exception (as applicable), that does not mean that such incentive automatically violates the statutes and is illegal. Contingency management incentive arrangements that do not comply with a safe harbor must be analyzed on a case-by-case basis for compliance with the Federal anti-kickback statute and Beneficiary Inducements CMP. In addition, incentives that are included in a service covered by a Federal health care program (*i.e.,* the coverage includes the incentive itself) would not implicate the Federal anti-kickback statute or the Beneficiary Inducements CMP, provided that the applicable billing and coverage rules are followed including collection of any applicable patient cost-sharing obligations. In addition, incentives offered as part of a CMS-sponsored model may qualify for protection under the new safe harbor at paragraph 1001.952(ii). Further, we are aware that some incentives may be provided pursuant to or in connection with other government-sponsored demonstrations or other government-sponsored programs (including studies initiated, organized, funded, and managed by the National Institutes of Health). Participation in and adherence to the requirements of such demonstrations or programs would be a relevant factor in assessing the intent of the parties and the risk posed by the arrangement.[63] Incentives offered to commercially insured patients or uninsured patients would not implicate the statutes. Application of the statutes is discussed in further detail in sections II.B and II.C of this preamble.

With respect to incentives in the form of cash or cash equivalents, we are concerned about heightened fraud and abuse risk. As noted in the OIG Proposed Rule, OIG historically has had significant concerns with allowing providers and others to offer cash or cash equivalents to patients, and our oversight and enforcement experience suggests that cash incentives can result in medical identity theft and misuse of patients' Medicare numbers, lead to inappropriate utilization (in the form of medically unnecessary items and services), and cause improper patient steering (including patients selecting a provider because the provider offers the most valuable incentives and not because of the quality of care the provider furnishes).[64]

Moreover, in the area of substance use disorder treatment, OIG and its law enforcement partners have substantial enforcement experience that demonstrates the pervasiveness of fraud in treatment programs that serve neither the best interests of patients nor taxpayers. For example, OIG has participated in enforcement actions resulting from allegations of significant fraud by substance use disorder treatment facilities, or ''sober homes,'' that take advantage of individuals with substance abuse disorders.[65]

We preclude cash or cash equivalents from protection under this safe harbor in recognition of the critical need to protect vulnerable patients from fraud. That said, as stated above, arrangements involving cash or cash equivalents used to promote adherence or healthy behavior modification do not necessarily violate the Federal anti-kickback statute; they would need to be evaluated under the anti-kickback statute on a case-by-case basis, including the intent of the parties. Parties may seek an OIG advisory opinion if they want assurance that their arrangement(s) comply with the statutes or would not be subject to OIG administrative enforcement sanctions, but having an advisory opinion is not mandatory. Declining to seek an OIG advisory opinion is not evidence that parties have improper intent under the Federal anti-kickback statute.

As stated above, in-kind incentives in connection with contingency management or other motivational programs can fit in the final safe harbor if all conditions are met. We note that offering incentives to patients as a reward for accessing care may not satisfy the prohibition on marketing and patient recruitment at paragraph 1001.952(hh)(6), depending on the facts and circumstances. We also emphasize that remuneration offered as a reward or incentive is not protected if it results in a beneficiary being furnished medically unnecessary care or inappropriate items or services reimbursed by a Federal health program, pursuant to the condition at paragraph 1001.952(hh)(3)(iv).

Finally, to the extent that existing safe harbors might not address all facets of contingency management incentive programs, we are considering addressing them in future rulemaking.

Comment: A commenter urged OIG to consider extending safe harbor protection to benefits such as direct payments from a provider to utility companies and the direct provision of technology (*e.g.,* electronic scales and tablets to provide continuing condition-specific education).

Response: Because the beneficiary does not directly receive cash or cash-equivalent remuneration, we consider the specific examples provided by the commenter to be in-kind remuneration, which may be protected by this safe harbor if the other conditions of the safe harbor are satisfied.

Comment: A commenter observed that Congress has recognized the value of providing incentive payments to patients in allowing Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program to make payments to patients who receive qualifying primary care services from providers participating in those ACOs.

Response: We recognize that the ACO Beneficiary Incentive Program, which is administered by CMS as part of the Medicare Shared Savings Program, allows an ACO to make incentive payments to beneficiaries of up to $20 per qualifying service as an incentive to

[63] *See, e.g.,* OIG, OIG Adv. Op. No. 08–14 (Oct. 2, 2008), *available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-14.pdf* (regarding a substance abuse treatment center's use of motivational incentives to reward a patient's achievement of certain treatment-related goals; in this advisory opinion, Requestor's program was developed and refined in connection with National Institute on Drug Abuse's government-sponsored research into implementation of motivational incentives as a treatment option, a fact that OIG viewed favorably).

[64] 84 FR 55275 (Oct. 17, 2019).

[65] *See, e.g.,* Press Release, U.S. Department of Justice, National Health Care Fraud and Opioid Takedown Results in Charges Against 345 Defendants Responsible for More than $6 Billion in Alleged Fraud Losses (Sept. 30, 2020), *https://www.justice.gov/criminal-fraud/hcf-2020-takedown/press-release.*

encourage utilization of medically necessary primary care services if certain eligibility, recordkeeping, and notification requirements are met. Nothing in the new patient engagement and support safe harbor would prevent ACOs from continuing to participate in that program or from structuring ACO Beneficiary Incentive Payment programs to satisfy the requirements of the new safe harbor set forth at paragraph 1001.952(kk), which protects payments under the ACO Beneficiary Incentive Program. Although we are not protecting similar incentives in this safe harbor, this decision does not reflect the programmatic value of the ACO Beneficiary Incentives.

The patient engagement and support safe harbor will protect tools and supports furnished outside of the context of a program administered and monitored by CMS. Without that programmatic oversight, we believe the safeguards in this final rule, including limiting safe harbor protection to in-kind remuneration, are appropriate and necessary to protect Federal health care programs and beneficiaries from harms associated with fraud and abuse.

Comment: A commenter urged OIG to update its 2016 Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries to revise its interpretation of ''nominal value'' from $15 per instance to $20 per instance, and from $75 in the aggregate per year to $100 in the aggregate per year.

Response: We decline commenter's request to update our guidance on ''nominal value'' [66] in this rulemaking. We note that our nominal value guidance focuses only on OIG's Beneficiary Inducements CMP authorities, and not the anti-kickback statute.

iii. Waiver or Reduction of Cost-Sharing Obligations

Summary of OIG Proposed Rule: In the OIG Proposed Rule, we sought comments on a variety of issues relating to potential safe harbor protection for waivers or reductions of patient cost-sharing obligations in different circumstances, including waivers or reductions of patient cost-sharing in the context of the proposed value-based framework. We also noted that the requirements related to cost-sharing in the Medicare and Medicaid programs are a programmatic matter; cost-sharing is required pursuant to statute, regulations, and other rules set forth by CMS and state Medicaid programs.

Summary of Final Rule: We are not finalizing a condition to protect cost-sharing waivers or reductions under this safe harbor.

Comment: Many commenters expressed support for protecting waivers of beneficiary cost-sharing obligations for remote patient monitoring, chronic care management, digital technologies that include care coordination functionality, and other care coordination services. A commenter argued that both patients and Federal health care programs benefit from waiving cost-sharing requirements for these items and services because reducing barriers to accessing preventive care can improve health outcomes for patients while also ensuring efficient use of taxpayer resources. Commenters also asserted that cost-sharing obligations can serve as a significant barrier to patient access for these and other care coordination items and services, and that providers' concerns regarding patients' fulfilling cost-sharing obligations could discourage providers from even offering these services. A commenter pointed out that protecting cost-sharing waivers could give flexibility to certain manufacturers to structure rewards programs that could incentivize patient behavior that may improve health outcomes, such as treatment adherence. One commenter noted that waivers of cost-sharing obligations are less prone to abuse than providing cash to patients but posited that waivers can still lead to undesirable effects such as cherry-picking and patient steering.

Commenters also noted that collecting cost-sharing amounts may be administratively burdensome for providers, and for certain items and services the cost of collection often exceeds the cost-sharing amount to be collected. In order to address this issue, a commenter recommended that OIG protect waivers of cost-sharing amounts when the amount owed by the beneficiary is nominal, similar to OIG's Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries, or that OIG amend its interpretation of ''reasonable collection efforts'' under section 1128A(i)(6)(A)(iii)(II) of the Act so that these collection efforts do not include situations where the cost of collection by the provider exceeds the cost-sharing amount that the provider would potentially collect.

Commenters also urged OIG to implement safe harbor protection for waivers or reductions of other types of cost-sharing obligations, including cost-sharing for services furnished through patient-centered medical homes and patient-centered specialty practices, such as visits that promote medication adherence, preventive care, and kidney disease education. A commenter suggested that OIG should protect full or partial cost-sharing waivers where care coordination arrangements result in cost savings to the health care system, which would allow patients to share in savings resulting from compliance with disease management or treatment programs.

A number of commenters urged OIG to protect waivers of IHS beneficiaries' cost-sharing obligations for items and services furnished by Indian health programs, noting that the imposition of cost-sharing obligations can be a barrier to care coordination for those patients.

Response: Cost-sharing waivers, or other tools and supports designed to effectuate a waiver of beneficiary cost-sharing, are not protected under the final patient engagement and support safe harbor. We appreciate commenters' suggestions regarding potential safe harbor protection for waivers or reductions of certain cost-sharing obligations, particularly in the context of value-based care and coordination of care. However, for a number of reasons we are not convinced that a safe harbor promulgated by OIG through regulation would be the appropriate mechanism to protect the waiver or reduction of a programmatic requirement. As we stated in the OIG Proposed Rule, beneficiary cost-sharing obligations are a programmatic requirement, and we do not believe it would be appropriate to broadly protect cost-sharing waivers that could obviate a programmatic requirement created by statute to the extent requested by commenters. On several occasions, Congress has enacted limited and individualized statutory protection for cost-sharing waivers. For example, Congress enacted an exception to the anti-kickback statute that allows pharmacies to waive Medicare Part D cost-sharing under certain conditions, and we have promulgated corresponding, implementing regulations.[67]

In addition, commenters requested OIG provide safe harbor protection for the waiver of beneficiary cost-sharing for certain items and services (*e.g.,* remote patient monitoring, chronic care management, digital technologies that include care coordination functionality, and other care coordination services). We do not think it would be appropriate or feasible for this rule to make

[66] *See* OIG, Office of Inspector General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016), *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf.*

[67] Section 1128B(b)(3)(G) of the Act; 42 CFR 1001.952(k)(3).

distinctions regarding cost-sharing waivers based on particular categories of services. We do not discern a reasonable basis for making such distinctions. We note that longstanding OIG guidance allows for waivers of cost-sharing amounts based on individualized, good faith determinations of financial need.

In the OIG Proposed Rule, we stated that we were considering protecting cost-sharing waivers for certain specified services (*e.g.,* care management services). We are not adopting the commenter's recommendation to waive nominal cost sharing amounts. As discussed above, we do not view a safe harbor to the Federal anti-kickback statute as an appropriate vehicle to address programmatic rules related to beneficiary cost sharing.

In addition, we did not propose to amend our interpretation of ''reasonable collection efforts'' under section 1128A(i)(6)(A)(iii)(II) of the Act and decline to do so in this final rule.

iv. Social Determinants of Health

Summary of OIG Proposed Rule: For reasons described in the OIG Proposed Rule, including the connection of social determinants to health outcomes and costs,[68] we proposed to protect at paragraph 1001.952(hh)(3)(i) an in-kind item, good, or service such as, among others, supports or services designed to identify and address a patient's social determinants of health. In the OIG Proposed Rule, we cited the existence of substantial evidence that ''unmet social needs'' related to social determinants of health such as transportation, nutrition, and safe housing play a critical role in health outcomes and expenditures,[69] two key policy goals of this rulemaking. We sought comment on which social determinants are most crucial to improving care coordination and transitioning to value-based care and payment.[70] We also sought comments on how or whether to protect tools and supports designed to address social determinants of health, including whether to make distinctions among various categories of social determinants or to list specific permissible tools and supports.

Summary of Final Rule: We are finalizing, with modifications, paragraph 1001.952(hh)(3)(i). The modifications remove the illustrative example related to social determinants of health from paragraph 1001.952(hh)(3)(i). Notwithstanding, the final rule at paragraph 1001.952(hh) protects in-kind tools and supports that identify and address a patient's social determinants of health, provided that the tools and supports otherwise meet all applicable safe harbor conditions, including, among others, the $500 annual cap, the requirement for a direct connection to the coordination and management of the care of the target patient population, the requirement that the tool or support is recommended by the patient's licensed health care professional, and the requirement that the tool or support advances at least one of the enumerated goals set forth at paragraph (hh)(3)(vi) of the final rule. The five enumerated goals ensure that protected tools and supports have a close nexus to care coordination, quality of care, and health outcomes for patients.

As with health-related technology and patient health-related monitoring tools and services, we are no longer including the specific example of tools and supports that identify and address social determinants of health in the final paragraph 1001.952(hh)(3)(i). Explicitly listing illustrative categories of protected remuneration is not necessary to effectuate the policy set out in the proposed rule that these categories and other types of tools and supports can be protected if all safe harbor conditions are met. This change ensures the final rule does not inappropriately limit the type or range of in-kind tools and supports that could be protected by this safe harbor. This will allow the licensed health care professional to determine the specific type of tool or support that works best for the patient, as long as all conditions of the safe harbor are met.

Comment: Numerous commenters urged us to extend explicit safe harbor protection to address various social determinants of health, focusing primarily on tools and supports to address food insecurity, housing instability, and transportation needs. Commenters also noted that identifying and addressing patients' social determinants of health through patient engagement tools and preventive care items will allow entities to improve patient outcomes while also reducing health care costs.

Response: We agree that these types of tools and supports have the potential to improve patient outcomes while producing savings to Federal health care programs and patients. Tools and supports to address the categories of social determinants cited by the commenters may be eligible for safe harbor protection if they meet all safe harbor conditions including, among others, one of the safe harbor's enumerated goals at paragraph 1001.952(hh)(3)(vi). For examples of how the safe harbor could protect tools and supports that identify and address social determinants of health, we refer readers to the response directly below. We are finalizing this safe harbor without including tools and supports designed to identify and address social determinants of health as an example of protected remuneration in the regulatory text. This change will ensure the final rule avoids inadvertently constraining the types or categories of in-kind tools and supports protected by this safe harbor in order to foster beneficial innovation.

Comment: We received a number of comments addressing the question of how to define social determinants of health and related tools and supports for the purpose of this new safe harbor. Many commenters urged us not to specify permissible tools and supports, but instead to adopt a flexible approach. Other commenters requested OIG provide a nonexclusive and nonexhaustive list illustrative of the types of permissible tools and supports that could receive protection under the safe harbor, indicating that such a list would provide clarity to the industry regarding the scope of tools and supports this safe harbor would protect without limiting flexibility and innovation. Another commenter sought clarification regarding how to interpret our proposed protection for tools and supports that address social determinants of health and other items and services such as preventive care items and services and health-related technology, including how to interpret the list of illustrative examples we provided in the preamble.

Commenters provided examples of a wide range of categories of social determinants of health and the tools and supports that commenters argued should be protected under this safe harbor, which they consider most crucial to improving coordination and management of care and transitioning to value-based care and payment. The social determinants of health—and tools and supports to address such social determinants of health—cited by commenters include food insecurity, housing instability, transportation, nutrition education, supervised exercise, fitness training programs, household or vehicle modifications to promote mobility and independence, addiction recovery programs, mental health programs, payment of utility bills, and supports related to interpersonal violence.

Some commenters offered extensive lists of social determinants of health relevant to specific health issues, such

[68] 84 FR 55723 (Oct. 17, 2019).

[69] 84 FR 55723 (Oct. 17, 2019).

[70] 84 FR 55724 (Oct. 17, 2019).

as determinants that impact musculoskeletal care or chronic diseases. Another commenter urged OIG to use the framework developed by the Kaiser Family Foundation to make distinctions among categories of social determinants using the following categories: (i) Economic stability; (ii) neighborhood and physical environment; (iii) food; (iv) community and social context; and (v) health care system. Another commenter suggested OIG reference services offered as supplemental benefits within Medicare Advantage as well as the special supplemental benefits for the chronically ill included in the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act.

Response: We appreciate commenters' suggestions regarding how best to identify and protect categories of social determinants of health and related tools and supports that should be protected under this safe harbor. We agree with the concern that an exclusive list of protected tools or supports in regulatory text could inappropriately constrain entities from offering the most useful types of tools and supports, and a rigid definition of social determinants of health could limit innovation related to tools and supports that may be protected by this final rule, if all conditions of the safe harbor are met. We are not providing a specific definition of ''social determinants of health'' for the purpose of this final rule, as one is not needed, nor are we providing an exclusive list of the types of tools and support that will receive safe harbor protection. We agree with the commenters that recommended flexibility.

We offer below illustrative, but not exhaustive, examples of tools and supports related to identifying and addressing patients' needs related to social determinants of health that may qualify under the safe harbor if all safe harbor conditions are met. We provide this list of representative tools and supports to readers to explain our interpretation of the safe harbor; we emphasize that this list is neither exhaustive nor does it point to the Government's view of the effectiveness of the listed examples. Furthermore, we remind readers that the safe harbor is specifically focused on the coordination and management of patient care. There are other important aspects of addressing social determinants of health that are not covered by this rulemaking because they do not relate to the coordination and management of patient care. In some cases, other safe harbors such as the local transportation safe harbor, or other exceptions to the Beneficiary Inducements CMP, such as the financial-need-based exception and the promote access to care exception (both found at paragraph 1003.110), may be available for incentives that address patients' needs related to social determinants of health.[71] OIG's advisory opinion process is also available, and OIG has issued several advisory opinions addressing areas such as nutrition, lodging, and transportation.

Illustrative examples of tools and supports related to social determinants of care that could be structured to fit in the safe harbor, depending on the facts and circumstances, include the following: Provision of in-kind transportation, such as transit vouchers or rideshares organized by the VBE participant; home modifications such as grab bars, air filters or purifiers, and other physical or structural modifications that allow patients to live safely at home; temporary housing for an individual experiencing homelessness or living far from a hospital following a surgical discharge; providing broadband access to a patient to enable remote patient monitoring or virtual care; grocery or meal delivery services, nutrition supplements, and nutrition education; exercise or fitness programs or equipment; vehicle modifications; incentives as part of addiction recovery programs, including peer-to-peer programs and contingency management programs; incentives as part of mental health programs; and supports related to interpersonal violence. For each of the preceding examples, all safe harbor conditions would need to be met, including that the tool or support advances one of the goals enumerated in paragraph 1001.952(hh)(3)(vi).

In contrast, some tools and supports that could help address needs related to social determinants of health would be very unlikely to fit in the safe harbor. For example, tools and supports related to finding employment or housing-related tools and supports of a routine nature, such as routine or ongoing rent or utility payments, are unlikely to meet the requirements that they be directly related to coordination and management of patient care, be recommended by the patient's licensed health care professional, and advance an enumerated goal at paragraph 1001.952(hh)(3)(vi).

We emphasize that the changes to the regulatory text ensure this final rule is agnostic about the specific types of in-kind tools or supports protected by this safe harbor. This will give licensed health care professionals flexibility to determine and recommend the tool or support that would best address a patient's social determinants of health to foster coordination and management of patient care.

Comment: A commenter urged OIG to identify an additional goal under paragraph 1001.952(hh)(3)(vi) for ''management of activities of daily living,'' to clarify that tools and supports may be protected if used to address social determinants of health.

Response: We are not adopting this suggestion. As explained above, in-kind tools and supports used to address social determinants of health may be protected by the safe harbor if they meet all safe harbor conditions. Depending on the specific facts and circumstances, in-kind tools and supports for the management of activities of daily living could meet several of the enumerated goals in paragraph (hh)(3)(vi) including, for example, goals related to adherence to a followup treatment plan, prevention or management of a disease or condition, and ensuring patient safety. Such tools and supports would need to meet all other safe harbor conditions as well. The goals proposed in the OIG Proposed Rule and finalized in paragraph 1001.952(hh)(3)(vi) are intended to have a close nexus to the coordination and management of patient care. Ensuring that beneficiaries have the support they need to manage activities of daily living is critically important. However, for purposes of this safe harbor, a separate goal related to ''management of activities of daily living'' would not have the same close nexus.

We note that nothing in this rule alters any existing program rules or benefits available to support activities of daily living.

In particular, some health care benefits, such as long-term care services covered by Medicaid, utilize assessments of activities of daily living to determine the appropriate level of care for a patient. This safe harbor does not affect those rules. Additionally, some long-term care benefits may also provide coverage for items or services to help manage a patient's activities of daily living that are similar or the same as the tools and supports protected by this safe harbor. Consistent with the discussion in section III.B.6.l on cost-shifting, if a provider furnishes covered

[71] We remind readers that exceptions to the definition of ''remuneration'' under the Beneficiary Inducements CMP apply only for the purposes of the definition of ''remuneration'' applicable to section 1128A of the Act (the Beneficiary Inducements CMP); they do not apply for purposes of section 1128B(b) of the Act (the Federal anti-kickback statute).

items or services that are covered by a Federal health care program and billed following normal rules, the provision of those items or services alone would not implicate the Federal anti-kickback statute.

v. Health-Related Technology and Patient Monitoring

Summary of OIG Proposed Rule: Proposed paragraph 1001.952(hh)(3)(i) included health-related technology and patient health-related monitoring tools and services as examples of permissible tools and supports.

Summary of Final Rule: We are not finalizing our proposal to include these examples in regulatory text. Paragraph 1001.952(hh)(3)(i) simply requires an in-kind item, good, or service, without qualifiers or examples. We confirm that health-related technology and patient health-related monitoring tools and supports can be protected remuneration if all safe harbor conditions are met.

Comment: Commenters were encouraged that the OIG Proposed Rule recognized wearable monitoring devices as ''health-related technology and patient health-related monitoring tools and services'' that were potentially protected tools and supports, noting the power of such technologies in managing chronic illness and promoting patient adherence. A commenter asked OIG to consider how to ensure that the safe harbor does not stifle innovative health care provider arrangements for care coordination implemented via remote patient monitoring. The same commenter urged OIG to reexamine what constitutes an inducement and help health care stakeholders better understand these regulations by offering FAQs, guidance, or web-based access to additional information.

Response: As noted above in the discussion relating to preventive care, we have simplified the safe harbor language to reflect the breadth of protected categories of remuneration. Accordingly, the safe harbor no longer specifically references health-related monitoring tools and services but instead requires that tools or supports are in the form of an in-kind item, good, or service that meets the other requirements of the safe harbor. This revision is in no way intended to limit the scope of remuneration protected by the safe harbor to exclude or otherwise limit health-related technology; rather, we intend the new text at paragraph 1001.952(hh)(3)(i) to reflect the breadth of tools and supports eligible for protection under the safe harbor.

We believe the safe harbor, including this broadened language, will expand opportunities for innovation in how industry stakeholders engage and support patients, including arrangements involving remote patient monitoring. For instance, tools such as connected scales or blood pressure monitors that track and transmit data to a patient's licensed health care professional, or applications that allow a patient's mobile devices to monitor activity or other health data, could be protected, if all other conditions of the safe harbor are satisfied.

Comment: Commenters sought clarification as to how telehealth tools and supports fit within the category of health-related technology. In particular, a commenter asked whether the new patient engagement and support safe harbor may be used to protect the provision of non-device-based telehealth platforms and aggregators. Another commenter urged OIG to clarify that, as a general matter, multifunction equipment could comply with the Federal anti-kickback statute through a safe harbor and exception to the Beneficiary Inducements CMP.

Response: In-kind telehealth supports can be protected under this safe harbor if the provision of such supports satisfies all of the safe harbor's conditions.[72] For instance, a smartphone that facilitates telehealth services with a patient's licensed health care professional, or a platform or software that facilitates telehealth services, may be a protected form of remuneration under this safe harbor if all safe harbor conditions are satisfied. The commenter's request for additional OIG guidance on whether the provision of multifunctional equipment would implicate the Federal anti-kickback statute and Beneficiary Inducements CMP is a fact-specific inquiry. Tools and supports that may be protected by this safe harbor could include multifunctional equipment, as long as the tool or support advances one of the enumerated goals at paragraph 1001.952(hh)(3)(vi).

Comment: A commenter urged that patient communication and counseling services are aligned with the spirit of the proposed safe harbor and requested confirmation that these services constitute patient health-related monitoring tools and services.

Response: We agree that patient communication and counseling services may qualify as protected in-kind remuneration if the conditions of the safe harbor are satisfied.

vi. Not Duplicative

Summary of OIG Proposed Rule: We solicited comments on whether to require the VBE participant to confirm that the tool or support is not duplicative of, or substantially the same as, tools and services the patient already has.

Summary of Final Rule: We are not finalizing this condition.

Comment: A commenter supported requiring the patient to confirm that the tool or support is not duplicative of something already owned by the patient. A commenter stated that restrictions related to providing duplicative tools or services that the patient already has are unnecessary in light of the proposed safe harbor requirement prohibiting the sale or diversion of the item or service. Moreover, some commenters stated that this type of requirement would prove difficult to implement because even if a patient has a similar device or service, it does not mean that it has enough or the correct technology to accomplish the VBE's or VBE participant's care objectives and goals. Some commenters stated that this condition would be difficult to interpret and enforce, and some commenters asserted that the provision of duplicative tools and supports would be unlikely to result in patient inducement. Another commenter highlighted concern related to any such condition's intersection with providing updated or upgraded tools and supports that might technically duplicate tools and supports to which a patient already has access. A commenter asked what would be considered duplicative or substantially the same, asking specifically whether an updated smartphone to support the use of a monitoring application would be duplicative if a patient already owns a cell phone. The same commenter also inquired whether providing other updated technology—such as a newer version of a patient's glucose monitor—would be considered duplicative.

[72] We acknowledge that Federal health care program coverage of telehealth services and other care provided remotely has expanded and the regulatory framework applicable to telehealth services and other virtual care has shifted, at least temporarily, since the publication of the OIG Proposed Rule. In particular, in response to the unique circumstances resulting from the outbreak of COVID–19, the Secretary determined, pursuant to section 319 of the Public Health Service Act, that a public health emergency (PHE) exists and has existed since January 27, 2020 (COVID–19 Declaration). *See* Department of Health and Human Services, Determination that a Public Health Emergency Exists (Jan. 31, 2020), *available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.* As a result of the PHE, various agencies have adopted temporary rules and guidance designed to ease access to telehealth services and other virtual care during the PHE. *See for example* CMS, Interim Final Rule with Comment Period, Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 19230 (Apr. 6, 2020).

A commenter stated that OIG should not require confirmation that the tools and supports provided to a patient are not duplicative of, or substantially the same as, tools and supports the patient already has, which the commenter believed fails to recognize that VBE participants may want to rely on the safe harbor to test the effectiveness of a particular tool or support.

Response: In this final rule, we are not adopting a requirement that a VBE participant confirm that a tool or support is not duplicative of, or substantially the same as, tools or supports the patient already has. We appreciate the concerns raised by commenters regarding the practical challenges in implementing this requirement, including that it is difficult to determine which tools or supports would be considered duplicative.

However, tools or supports that are duplicative of items or services that a patient already owns or has access to may not advance one of the goals listed at paragraph 1001.952(hh)(3)(vi) and therefore may not be eligible for safe harbor protection. For example, providing a patient with a new smartphone would not necessarily advance any of the enumerated goals if the patient already has a cell phone with sufficient functionality. For instance, the licensed health care professional's recommendation of a smartphone to transmit medication adherence reminders may not *advance* the patient's adherence to a drug regimen if the identified need for the smartphone—to transmit medication adherence reminders—is already achievable with the patient's existing cell phone. On the other hand, provision of a smartphone could promote adherence to a treatment regimen determined by the patient's licensed health care professional (pursuant to the goal listed at paragraph 1001.952(hh)(3)(vi)(A)) if, for example, the new smartphone adds functionality needed for remote monitoring that is not available on the patient's existing cell phone.

In response to the comment regarding using the patient engagement and support safe harbor to test the effectiveness of tools or supports, the safe harbor protects remuneration that advances one or more of the enumerated goals under paragraph 1001.952(hh)(3)(vi). While protection under this safe harbor is not conditional on *achieving* one or more of these enumerated goals, a tool or support would not be eligible for safe harbor protection without a reasonable basis that it would advance at least one of the enumerated goals. The requirement to advance one or more of the listed goals means, at a minimum, that the VBE participant reasonably expects the tool or support to be effective in advancing a goal.

g. Marketing and Patient Recruitment

Summary of OIG Proposed Rule: We proposed a condition at proposed paragraph 1001.952(hh)(3)(iv) that would exclude from safe harbor protection tools or supports used for patient recruitment or marketing of items or services to patients. Separately, we sought comment on whether to include a condition that would prohibit advertising of the patient engagement tools or supports offered by a VBE participant. We solicited comments on how best to preclude using tools and supports as a marketing or advertising strategy to recruit patients or otherwise influence referral sources, patients or otherwise, while still permitting beneficial educational efforts and activities that promote patient awareness of care coordination activities and available tools and supports.

Summary of Final Rule: We are finalizing, with modifications, the proposed condition at paragraph 1001.952(hh)(6). Under the final rule, neither the VBE participant, nor an eligible agent of the VBE participant, may use the patient engagement tools or supports to market other reimbursable items or services or for patient recruitment purposes. The final safe harbor condition clarifies the limitation on marketing and patient recruitment consistent with our intent in the OIG Proposed Rule to preclude protection of tools and supports used solely for patient recruitment purposes or used to market other reimbursable items and services to patients. The final condition clarifies that the marketing prohibition only applies with respect to the marketing of items and services reimbursable by Federal health care programs. Providing remuneration to patients in order to market items or services not reimbursable by Federal health care programs is unlikely to implicate the anti-kickback statute and therefore would not need safe harbor protection. As discussed further below, this condition does not preclude a VBE participant from educating patients, such as providing objective patient educational materials to a patient or engaging in objective patient informational activities with respect to patients in the target population.

Comment: Commenters generally supported our proposed prohibitions on marketing and patient recruitment but urged OIG to clarify that certain activities would not be prohibited, such as providing education and information to established patients or members of the target patient population about available resources, tools, and supports. For example, a commenter suggested that a health care facility operating an onsite food pantry should be able to post basic information, such as the food pantry's hours of operation, to ensure patient access. Another indicated that providers should be able to educate beneficiaries about how to access care and to increase awareness and utilization of services by describing available tools and supports on a provider's website or by offering free marketing items such as refrigerator magnets, stickers, and notepads.

Other commenters opposed these conditions altogether or requested that we clarify the delineations between prohibited marketing, advertising, and patient recruitment as opposed to permissible patient education and awareness activities. Commenters warned that dissemination of information to patients and their providers is necessary for patients to achieve the health benefits intended by a particular patient engagement program. A commenter added that restricting advertising requires providers to determine which patients may benefit from available resources, rather than empowering patients to self-identify whether they may benefit from a given tool or support.

Response: We agree with the commenters who supported conditions relating to marketing and patient recruitment, and we are finalizing these concepts in a revised safe harbor condition at paragraph 1001.952(hh)(6). The patient engagement and support safe harbor does not protect the provision of tools or supports if the VBE participant uses the tools or supports to market other reimbursable items or services or for patient recruitment purposes. As noted in the proposed rule, the proposed condition was designed to preclude a VBE using a tool or support to market other reimbursable items and services, or using a tool for patient recruitment while permitting beneficial educational efforts and activities that promote patient awareness of care coordination activities and available tools and supports. We do not intend to protect tools or supports that serve solely as patient recruitment incentives.[73]

This condition does not preclude providers from educating their patients or otherwise providing information about available tools and supports to established patients. In other words, this

[73] 84 FR 55727 (Oct. 17, 2019).

condition does not limit providers from offering objective information, education, and reminders to their patients, nor does it limit providers from offering tools and supports designed to educate patients and increase awareness and utilization of appropriate services.

As an example, the following activity would not violate this condition: A physician VBE participant informs a patient with asthma that clean air in the home is important for keeping asthma symptoms under control. The physician explains that clean air conditioning filters and other air purifying machines are important for keeping the air in a home clean and healthy. The physician informs the patient that the VBE has a program to provide air filters, and the patient may be eligible to receive free air filters provided by the physician.

However, the safe harbor does not protect a tool or support if used to recruit patients or used to market other reimbursable items or services. This condition protects against abusive marketing schemes where the patients are inappropriately induced to select providers or use items or services because they are being provided with free or low-cost tools and supports. Importantly, the patient engagement and support safe harbor protects the provision of tools and supports to patients; it does not protect any marketing, advertising, or patient recruitment arrangements.

As with the care coordination arrangements safe harbor's marketing and patient recruitment provision discussed in section III.B.3.j we use the terms marketing (*e.g.,* promoting or selling something), recruitment (*e.g.,* enlisting someone to do something), and education (*e.g.,* informing, instructing, or teaching) in accordance with their common sense meanings. Additionally, we consider ''advertising'' to be a subset of ''marketing,'' so the prohibition of using tools or supports to market other reimbursable items or services also prohibits advertising. This approach best allows flexibility for VBE participants to engage in appropriate educational efforts. We offer illustrative examples in response to comments to aid stakeholders in applying the safe harbor provision.

For example, a VBE participant could operate a non-billable diabetes remote monitoring program to help patients manage their diabetes and coordinate their care. As part of the program, the VBE participant offers patients with diabetes a free tablet to facilitate the remote monitoring program. Should the VBE participant seek to protect the tablet under this safe harbor, it would need to satisfy the marketing and patient recruitment condition at paragraph 1001.952(hh)(6). To illustrate the scope of this condition, we offer the following examples of educational activities that would comply with this condition. First, the VBE participant may counsel a patient with diabetes about the benefits of the non-billable remote monitoring program and explain that such program includes a free tablet to facilitate the program. Second, the VBE may explain that the tablet is used to convey information such as nutritional information, recipes, wellness tips, and appointment reminders. In these illustrative examples, the VBE participant is not using the tablet to market other reimbursable items or services or for patient recruitment.

By contrast, if the VBE participant uses the tablet to send patients text messages and notifications to induce them to obtain tests, equipment, supplies, or other reimbursable items and services, the condition at paragraph 1001.952(hh)(6) would not be satisfied; the VBE participant is using the tool and support (the tablet) to market other reimbursable items and services. Similarly, if the VBE participant advertises that patients will receive a free tablet if they register for the remote monitoring program and receive services, the VBE participant is using the tool and support to recruit patients and the provision of the tablet does not qualify for safe harbor protection. It would be the same result if the VBE participant used the provision of the tablet to market other reimbursable services or recruit patients through door-to-door marketing, telephone solicitations, direct mailings, or through sales pitches masquerading as ''informational'' sessions.

In response to commenters, we clarify that notification to an entire target patient population about the availability of tools and supports does not necessarily raise concerns under this condition. Whether a notification to an entire patient population satisfies this condition would require a highly fact-specific assessment. For example, if a physician used an announcement to an entire target patient population about the availability of free air conditioning filters if those patients come in for an office visit (*e.g.,* as an inducement to attract patients to schedule an appointment billable to a Federal health care program), that would constitute prohibited marketing or patient recruitment, even if the announcement also had an educational purpose. In contrast, if the announcement provided information on the need for asthma patients to ensure the air in the home is clean and to contact the physician for further information, that type of notification would not violate this condition. Again, we highlight that whether any particular communication satisfies this marketing condition would require a highly fact-specific assessment.

Among the examples described by the commenters, a hospital posting general information such as the hours of operation of its food pantry to make patients aware of when the food pantry is open and enhance patient access would not run afoul of this condition. Providing free marketing items as described by a commenter such as refrigerator magnets, stickers, and notepads likely would not be protected by this safe harbor for multiple reasons. If provided for the purpose of marketing or patient recruitment, such items would not meet this condition. Furthermore, these items are unlikely to advance one of the enumerated goals at paragraph 1001.952(hh)(3)(vi) or have a direct connection to the coordination and management of care of the target patient population.[74]

In response to the commenter who asserted that restricting advertising requires providers to determine which patients may benefit from available resources, rather than empowering patients to self-identify whether they may benefit from a given tool or support, we note that this condition is intended to preserve patient choice and protect vulnerable patients from the undue influence of coercive marketing. We also remind readers that any protected tool or support must satisfy the other conditions of the safe harbor as well, including that the patient engagement tool or support is recommended by the patient's licensed health care professional and advances one or more of the goals enumerated in the safe harbor. The protections in the safe harbor are designed to emphasize the patient's relationship with their provider in developing plans for treatment and care and the appropriate provision of tools and supports.

[74] We note, however, that such items may be excluded from the definition of remuneration under the Beneficiary Inducements CMP if they are of nominal value. *See for example* 65 FR 24411 (Apr. 26, 2000), *available at https://oig.hhs.gov/authorities/docs/cmpfinal.pdf,* and Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August 2002, *available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf* (Special Advisory Bulletin); Office of Inspector General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016), *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf.*

Consequently, the final safe harbor preserves patient choice and empowerment by relying on close communication and collaboration between patient and provider.

A prohibition on marketing and patient recruitment serves as an important protection against inappropriate patient steering and overutilization of federally reimbursable items and services. Our enforcement experience demonstrates that using tools and supports to recruit patients or to otherwise market reimbursable items and services presents a risk of harms associated with fraud and abuse (*e.g.,* overutilization, provision of unnecessary services to patients, and theft of patient's medical identity information).

We highlight that this prohibition extends to eligible agents of the VBE participant. More specifically, to qualify for safe harbor protection, neither the VBE participant *nor any eligible agent* may exchange or use the patient engagement tools or supports to market other reimbursable items or services or for patient recruitment purposes. Under paragraph 1001.952(hh)(2), the patient engagement tool or support may be furnished directly to the patient (or the patient's caregiver, family member, or other individual acting on the patient's behalf) by a VBE participant that is a party to the value-based arrangement or its eligible agent. The modification of the marketing and patient recruitment prohibition in paragraph 1001.952(hh)(6) reflects the changes to paragraph 1001.952(hh)(2) related to eligible agents. The marketing and patient recruitment prohibition applies equally to the VBE participant and to the eligible agent that may be furnishing the tool or support as an agent of the VBE participant. For example, this final rule precludes safe harbor protection for tools and supports used by a patient recruiter to induce or recruit beneficiaries to receive items or services reimbursed by a Federal health care program.

Comment: A commenter warned that an overly broad limit on advertising could be a barrier to providers giving basic information to patients. The commenter noted that OIG recognized this risk by limiting the scope of its advertising prohibition in the local transportation safe harbor, which explicitly allows posting shuttle route and schedule details.

Response: First, we remind readers that arrangements need not have safe harbor protection to be lawful, and we observe that many health care entities lawfully provide basic information to patients (which may not even implicate the Federal anti-kickback statute) and even market services without the benefit of a safe harbor. Second, we believe the final prohibition on marketing and patient recruitment is not overly broad. It prohibits using patient engagement tools and supports to market other reimbursable items and services or for patient recruitment. It does not limit providers giving basic information directly to their patients; indeed, as explained above, many types of basic information would not even implicate the Federal anti-kickback statute (*e.g.,* appointment reminders and mailings explaining the best hygiene practices to prevent influenza).

As the commenter states, the local transportation safe harbor provides protection for a shuttle service that is not marketed or advertised (other than posting necessary route and schedule details). We do not believe a specific exception, similar to the route and schedule details exception included in the shuttle services provision of the local transportation safe harbor, is needed in the patient engagement and support safe harbor, nor would such an exception be feasible to address the wide range of tools and supports potentially protected by this safe harbor. The final safe harbor's condition related to marketing and patient recruitment does not prohibit a VBE participant from providing basic information relating to available patient engagement tools and supports to patients.

For example, a hospital that also runs a food pantry could post the hours of operation of a food pantry. In contrast, should the hospital conduct a general advertisement to the public indicating, for example, that it has a free food program available to patients with diabetes (the target patient population) who come to the hospital to receive services, providing the support in the form of the free food program would fail to satisfy this condition and would not be protected by this safe harbor.

We emphasize that the provision of tools and supports to Federal health care program beneficiaries by certain entities (which could be VBE participants consistent with revisions made by this final rule)—such as a social services agency that does not bill Federal health care programs—would not implicate the Federal anti-kickback statute and, consequently, would not require safe harbor protection.[75] Therefore, such entities would not be subject to this marketing and patient recruitment condition.

Comment: A commenter urged OIG to ensure that the safe harbor allows sufficient flexibility to inform patients of the types of interventions designed to address social determinants of health that the VBE participant offers to support patients in achieving improved health outcomes and to furnish the best possible patient care. The commenter highlighted that in the context of tools and supports designed to address unmet social needs, patients may be reticent to self-identify absent appropriate outreach and advertising due to potential social stigmas associated with such needs. A commenter stated that a safe harbor condition prohibiting advertising could: (i) Reduce the ability of patients and providers to make fully informed decisions; (ii) lower the number of patients who have access to beneficial tools and supports; and (iii) hinder the ability to achieve the entity's value-based goals.

Response: The safe harbor condition prohibiting use of the patient engagement tools and supports to market other reimbursable items and services or for patient recruitment is not intended to constrain a licensed health care professional from informing patients of the types of available tools and supports. The safe harbor also would not prohibit other types of VBE participants from providing educational information about available tools and supports to patients in the target population.

Comment: A commenter asserted that a facility should be able to advertise the patient engagement tools and supports it offers, and if a patient elects a certain facility on that basis, then the patient has demonstrated active engagement in their care options.

Response: We recognize the importance of activated and engaged patients and consumer choice. As previously stated, potential donors may provide educational information and inform patients about the availability of engagement tools and supports. This condition prohibits only using tools and supports to market other reimbursable items and services or for patient recruitment. This final condition is designed to prevent VBE participants from influencing patients' decision-making regarding billable health care items and services based on the offer of free tools and supports. We are

[75] We recognize the possibility that a hospital or other entity that bills Federal health care programs could provide funding to an entity that does not bill Federal health care programs in order to support the provision of tools and supports to Federal health care program beneficiaries. Such funding could constitute an indirect financial relationship between the funding source and the beneficiary that could implicate the Federal anti-kickback statute and, if so, that relationship would need to be assessed separately.

concerned that patients might be coerced into selecting items and services that are not in their medical best interests. We emphasize, however, that nothing in this final rulemaking constrains patient decision-making; notably, patients are free to select (or decline to select) providers based on their participation in a VBE, on the care coordination and management services they furnish, or on the tools and supports they offer.

Comment: A commenter noted that a prohibition on advertising could disproportionately impact skilled nursing facilities and assisted living facilities whose patients are more likely to rely upon traditional advertising methods to understand their treatment options and alternatives.

Response: This condition restricts VBE participants who wish to use the safe harbor from using the tools and supports to market other reimbursable items or services (*e.g.,* an advertisement that offers to provide a free smartphone after a patient receives a service) or using such tools for patient recruitment. It does not prohibit a VBE participant, which could be a skilled nursing facility or assisted living facility, from otherwise advertising or marketing the patient care items and services they offer.

h. Direct Connection

Summary of OIG Proposed Rule: At proposed paragraph (hh)(3)(ii), we proposed that the tool or support furnished to the patient must have a ''direct connection'' to the coordination and management of care of the target patient population. We proposed to interpret ''direct connection'' to mean that the VBE participant has a good faith expectation that the tool or support will further the coordination and management of care for the patient. We solicited comments on whether to require a ''reasonable connection'' instead of a ''direct connection.'' We also solicited comments on an alternative proposal that would have required the VBE participant to make a *bona fide* determination that an arrangement to provide tools and supports is directly connected to the coordination and management of care for the patient. We solicited comments on whether the ''direct connection'' should be to any of the four value-based purposes described at proposed paragraph 1001.952(ee)(12)(vii) instead of requiring a direct connection to the coordination and management of care for the patient.

Summary of Final Rule: We are finalizing the condition, without modification, at paragraph 1001.952(hh)(3)(ii). Specifically, any protected tool or support must have a ''direct connection'' to the coordination and management of care of the target patient population. We are not finalizing any of the alternative proposals considered in the OIG Proposed Rule.

Comment: A number of commenters supported our proposal to require that any protected tool or support furnished to a patient have a direct connection to the coordination and management of care.

Response: We are finalizing this condition as proposed. As we explained in the OIG Proposed Rule, we do not believe it should be difficult for a VBE participant providing the patient engagement tool or support to clearly articulate the nexus between the tool or support and the coordination and management of care.

Comment: We received several comments recommending that we require only a ''reasonable connection'' to coordination and management of care, rather than a ''direct connection.'' Many commenters expressed a preference for the ''reasonable connection'' standard because it gives entities greater flexibility in the provision of patient engagement tools and supports and is better aligned with the standard that a VBE participant must have a good faith expectation that the tool or support will promote the VBE's objectives. A commenter opposed the ''reasonable connection'' alternative because it would weaken the partnership between providers that are collaborating to coordinate and manage a patient's care.

Response: We decline to modify the condition to require only a ''reasonable connection.'' The safe harbor protects the provision of potentially valuable in-kind remuneration furnished to patients. It is appropriate for the offerors of potentially valuable remuneration to carefully evaluate the nexus between the tool or support and the coordination and management of patient care. In the final rule, we opted for the ''direct connection'' standard, which will ensure that the remuneration is closely linked to the goals of the Regulatory Sprint, including promoting care coordination and value-based care. In particular, the final safe harbor is designed to protect tools and supports that are designed to result in higher value and better coordinated care. The ''direct connection'' standard will help ensure that protected remuneration specifically and intentionally advances the goals of the Regulatory Sprint over other possible objectives.

Comment: One commenter supported a condition requiring the VBE to make a *bona fide* determination that tools or supports have a direct connection to the coordination and management of care for a patient. However, numerous other commenters urged OIG not to adopt such a requirement, warning that it would be unduly burdensome and create administrative hurdles that would unnecessarily duplicate the determination made by a VBE in establishing value-based activities of the VBE and the role of the VBE participants in carrying out those activities.

Response: To avoid introducing unnecessary administrative burdens, and because we believe the other safeguards sufficiently mitigate the risk of patient harm and program integrity concerns, we are not finalizing a requirement—considered in the preamble to the OIG Proposed Rule—that the VBE make a *bona fide* determination that the tool or support has a direct connection to the coordination and management of care. We note, however, that while safe harbors are voluntary, parties that seek protection for tools and supports under this safe harbor must strictly satisfy each of the safe harbor's conditions, including the requirement that the tool or support has a direct connection to the coordination and management of care. The VBE and VBE participants may establish satisfaction of this condition in a variety of ways without such a *bona fide* determination; of course, making such a *bona fide* determination could support satisfaction of this safe harbor condition.

Comment: Several commenters suggested that OIG broaden the safe harbor to protect tools and supports that are directly connected to any of the four value-based purposes articulated in proposed paragraph 1001.952(ee)(12)(vii), rather than requiring a direct connection to a single value-based purpose, that is, coordination and management of patient care. Commenters suggested that this would provide greater flexibility for entities to offer tools and supports connected to the other three value-based purposes.

Response: We appreciate the commenters' input. However, we respectfully decline to adopt the commenters' suggestion. We believe the safe harbor is appropriately limited to the protection of tools and supports that are directly connected to the coordination and management of care, which empowers patients to fully participate in the care coordination activities that are the spirit of the

Regulatory Sprint. The other three value-based purposes described in paragraph 1001.952(ee)—improving the quality of care; appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care; and transitioning the health care delivery and payment systems to value-based care—are purposes that the applicable VBE participants, not patients, are in the best position to deliver.

In contrast, the coordination and management of care more directly relates to the patient engagement goals of this safe harbor. At paragraph 1001.952(ee)(14)(i)), this final rule defines ''coordination and management of care'' to mean the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population. This definition provides sufficient flexibility in designing arrangements for patient engagement that would be protected by this safe harbor because a broad range of tools and supports could be tailored to improving health outcomes and achieving safer and more effective care, while advancing one of the five enumerated goals at paragraph 1001.952(hh)(3)(vi). For instance, a program to provide grab bars or handrails to patients recovering from knee surgery to prevent falls at home could be properly tailored to improving health outcomes for these patients and designed to achieve safer, more effective care for this population.

Comment: A commenter sought clarification regarding when an item has a direct connection to coordination and management of care, specifically requesting a list of scenarios that would qualify. Another commenter suggested that we not finalize a description of specific tools or supports that would be considered to have a direct connection to the coordination and management of care because doing so could frustrate the goals of fostering flexibility, adaptability, and innovation.

Response: We agree with the commenter who suggested that we not finalize a description of specific tools or supports that would be considered to have a direct connection to the coordination and management of care. Consequently, we decline to provide a list of scenarios linking which tools and supports would qualify as having a direct connection to the coordination and management of a patient's care. In taking this approach, we hope to foster innovation and allow VBEs and VBE participants flexibility in appropriately identifying the nexus between the tool or support and the coordination and management of care. Revisiting our example of providing grab bars to patients recovering from knee surgery, the tool or support in that example has a direct connection to the coordination and management of care because it is intended to prevent falls and therefore provides safer and more effective care for the target patient population (knee surgery patients).

i. Medical Necessity

Summary of OIG Proposed Rule: In the OIG Proposed Rule's paragraph 1001.952(hh)(3)(v), we proposed that the tool or support must not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program.

Summary of Final Rule: We are finalizing, without modification, this condition and relocating it to paragraph 1001.952(hh)(3)(iv).

Comment: A hospital association supported our proposal to protect only tools and supports that do not result in medically unnecessary or inappropriate items or services reimbursed by Federal health care programs.

Response: We are finalizing this safeguard as proposed at paragraph 1001.952(hh)(3)(iv).

Comment: A commenter stated that any incentives protected by the final safe harbor should not be limited to incentives furnished to patients for attendance at medically necessary primary care or other clinically appropriate medical appointments, but also expanded to incentives for participating in community-based services that could impact clinical outcomes through addressing patients' social determinants of health.

Response: This safe harbor protects tools and supports that advance one or more enumerated goals set out at paragraph 1001.952(hh)(3)(vi), which include goals related to adherence to treatment regimens and followup care plans, and prevention and management of diseases and conditions. For a specific discussion of our treatment of tools and supports that address social determinants of health, please see the discussion at III.B.6.f.iv. of this preamble. To qualify for protection under the safe harbor, any incentives for participation in community-based services also would need to meet all other safe harbor conditions, including the condition that the remuneration cannot result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program. We also note that such community-based services would need to be recommended by the patient's licensed health care professional (per the condition at paragraph 1001.952(hh)(3)(v)) and have a direct connection to the coordination and management of care of the target population (per the condition at paragraph 1001.952(hh)(3)(ii)).

j. Licensed Health Care Professional Recommendation

Summary of OIG Proposed Rule: We proposed a safe harbor condition at proposed paragraph 1001.952(hh)(3)(vi) that would provide safe harbor protection only for tools or supports recommended by the patient's licensed health care provider. Relatedly, we sought comments on whether to require a written certification, under 18 U.S.C. 1001 and 1519, from a patient's licensed health care provider certifying that the particular tool or support is recommended solely to treat a documented chronic condition of a patient in a target patient population.

Summary of Final Rule: We are finalizing, with modification, this condition at paragraph 1001.952(hh)(3)(v). Based on public comment, we are revising the language to clarify that the tool or support must be recommended by the patient's licensed health care ''professional'' rather than ''provider.'' The term ''provider'' is often used to mean a hospital or other entity that furnishes institutional health care services. We believe ''professional'' is a clearer description of our intent in the OIG Proposed Rule that this requirement emphasizes the importance of a health care professional's medical judgment, as well as the patient's relationship with a health care professional. We have made conforming changes in each enumerated goal in paragraph 1001.952(hh)(3)(vi) that referenced a licensed health care provider. We are not finalizing the written certification requirement.

Comment: A trade association representing physicians supported the proposal to require that a tool or support must be recommended by the patient's licensed health care provider. Another commenter stated that this requirement is a key fraud and abuse protection to ensure that the safe harbor is not used for improper purposes such as marketing or patient recruitment, or to steer patients to particular treatments. A commenter also noted that this requirement helps ensure the centrality of the patient-provider relationship.

Another commenter expressed concern that a safe harbor condition requiring a licensed health care provider's recommendation would lead to underutilization of valuable tools and supports to treat social comorbidities. The commenter stated that many tools and supports that address social comorbidities do not stem from a single condition in isolation and, therefore, may not be evident to a treating clinician. Another commenter warned that this requirement could deter use of the new safe harbor because physicians do not typically recommend the types of tools and supports that would be most beneficial to patients. More often, according to the commenter, social workers, case workers, or others who may not be licensed clinicians would be in a better position to recommend such patient tools, including those that would address social determinants of health.

A commenter also urged OIG to include a requirement that clinicians offering any patient engagement tools and supports instruct patients on how to use them appropriately.

Response: We agree with commenters who support the condition because it protects against harms resulting from fraud and abuse and supports the centrality of the patient-provider relationship. As we explained in the preamble to the OIG Proposed Rule, this condition is designed to ensure that the remuneration is specifically focused on patient care and to underscore the importance of quality of care, the health care provider's medical judgment, and the patient's relationship with their provider in developing plans for treatment and care. The condition also ensures that the professional recommending the tool or support has undergone some degree of review and is subject to some level of oversight by a licensing body.

In response to the assertion that this condition would lead to underutilization of valuable services to treat social comorbidities, we believe the patient's licensed health care professional is in the best position to determine whether the tool or support is directly connected to the coordination and management of the patient's care, advances an enumerated goal at paragraph 1001.952(hh)(3)(vi), and will not result in medically unnecessary or inappropriate reimbursable items and services, as required by the safe harbor. The licensed health care professional recommending the tool or support can be any type of licensed health care professional, which should be sufficiently broad to ensure this safe harbor protects beneficial patient engagement tools and supports, including those cited by commenters in various submissions. We recognize that social workers, case workers, and others who may not be licensed clinicians play an important role in patient care and are often well-positioned to recommend patient tools, including those that would address social determinants of health. However, for purposes of this safe harbor, we are requiring a recommendation by a licensed health care professional for the reasons noted above.

We did not propose a definition of ''licensed health care provider'' or ''licensed health care professional.'' We intended to require the recommendation of a licensed health care professional, who would be a person chosen by the patient. The term ''licensed health care professional'' could include, for example, the following health care professionals, assuming they are appropriately licensed by an appropriate State licensing body for each respective profession: Physicians (including doctors of medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, and optometry); osteopathic practitioners; chiropractors; physician assistants; nurse practitioners; clinical nurse specialists; certified registered nurse anesthetists; physical therapists; occupational therapists; clinical psychologists; qualified speech-language pathologists; qualified audiologists; and registered dietitians or nutrition professionals.[76]

Comment: A commenter warned that requiring a licensed provider's recommendation could incentivize a provider to recommend a tool or support for which the provider can subsequently receive remuneration.

Response: To the extent the tool or support is a billable item or service, we would expect the provider to bill appropriately. The tool or support would not require safe harbor protection because it would be furnished by the provider as a covered service. If the provider were to waive any beneficiary cost-sharing, such cost-sharing waiver would not be protected by this safe harbor.

Comment: We solicited comments on whether to require a written certification, under 18 U.S.C. 1001 and 1519, from a patient's licensed health care provider certifying that the particular tool or support is recommended solely to treat a documented chronic condition of a patient in a target patient population. A commenter opined that requiring a licensed health care provider to document in writing their recommendation of the tool or support along with the justification, and requiring the offeror to maintain this documentation, is a reasonable safeguard. The commenter surmised that such documentation need not be in the form of a prescription or physician referral but could take the form of a recommendation that is documented in the care plan or approved by the care team. A commenter supportive of the certification requirement recommended that it be enforced through administrative or civil penalties, rather than potential criminal liability under 18 U.S.C. 1001 and 1519. Other commenters warned that imposing a certification requirement would be overly burdensome and could have a chilling effect on provider recommendations, even where the benefits of the tool or support are clear.

A commenter warned that requiring physicians to certify that a tool or support is used to treat a documented chronic condition could lead to a fragmented approach that looks at each condition in isolation, rather than offering coordinated support for all of a patient's health care needs.

Response: We are not finalizing a requirement that the patient's licensed health care professional certify that the tool or support is recommended solely to treat a documented chronic condition. The final safe harbor includes a number of other conditions designed in combination to safeguard against the risk of harms resulting from fraud and abuse including, among other conditions in the safe harbor, that the patient engagement tool or support must have a direct connection to the coordination and management of care, be recommended by the patient's licensed health care professional, and advance one or more enumerated goals.

Comment: Commenters also noted that the proposed certification requirement, especially with criminal penalties attached, would create a significant barrier to providing patient engagement tools and supports under this safe harbor. In addition, commenters cited concerns that a focus on documented chronic conditions would inappropriately narrow the protections afforded by this safe harbor.

Response: As stated above, we are not finalizing a requirement that the patient's licensed health care professional certify that the tool or support is recommended solely to treat a documented chronic condition. We

[76] This illustrative list of health care professionals includes professionals eligible as of 2020 to participate in the Merit-based Incentive Payment System (MIPS), *available at https://qpp.cms.gov/mips/how-eligibility-is-determined.*

believe the other safeguards are sufficient to allow innovative tools and supports for a wide array of enumerated goals while safeguarding against the harms resulting from fraud and abuse.

k. Advances Specified Goals

Summary of OIG Proposed Rule: Under the proposed condition at paragraph 1001.952(hh)(3)(vii), the tools and supports must advance one or more of the following enumerated goals: (i) Adherence to a treatment regimen as determined by the patient's licensed health care provider; (ii) adherence to a drug regimen determined by the patient's licensed health care provider; (iii) adherence to a followup care plan established by the patient's licensed health care provider; (iv) management of a disease or condition as directed by the patient's licensed health care provider; (v) improvement in measurable evidence-based health outcomes for the patient or the target patient population; or (vi) ensuring patient safety.

Summary of Final Rule: We are finalizing, with modifications, the requirement at paragraph 1001.952(hh)(3)(vi). Specifically, we are not finalizing the proposed goal relating to improvement in measurable evidence-based health outcomes for the patient or for the target patient population because it is largely captured by the other goals. The final rule revises the goal of ''management of a disease or condition'' to read ''prevention or management of a disease or condition'' to incorporate the element of prevention that was included at proposed paragraph 1001.952(hh)(3)(i). We are replacing references in this section to ''licensed health care providers'' with ''licensed health care professionals'' consistent with the preamble discussion in the previous section regarding this terminology.

Comment: Several commenters supported protection for these enumerated goals and appreciated that we did not specify which tools and supports would advance the specific goals to allow flexibility for VBE participants and promote innovation in patient engagement mechanisms, tools, and supports, particularly with respect to rapidly evolving technologies. A commenter requested that OIG add protection for adherence to a ''prevention regimen'' and prevention of a disease to the safe harbor's list of specified goals. Another commenter noted that the enumerated goals proposed could limit the offering of innovative tools and supports designed to address social determinants of health because such tools and supports may not directly link to the goals set forth in the OIG Proposed Rule.

Response: We are finalizing these goals as proposed, with the omission of the proposed goal relating to evidence-based health outcomes and modifications to include prevention of a disease or condition and to use the term licensed health care professionals. To avoid inadvertently limiting which tools and supports advance specified goals and provide VBE participants flexibility and the opportunity to innovate, we are not providing an exhaustive list of tools and supports. Indeed, one particular patient engagement tool may satisfy a number of these enumerated goals. For instance, a device or program that reminds a patient to take a medication or attend a scheduled office visit might advance the goals related to adherence to a treatment regimen, drug regimen, or follow-up care plan, or advance goals related to prevention or management of a disease or ensuring patient safety depending, in part, on the functionality and purposes of the device or program. In response to a commenter's suggestion, we revised the goal at paragraph 1001.952(hh)(3)(vi)(D) to read ''the *prevention* or management of a disease or condition'' so that this safe harbor is available to protect preventive items, goods, or services that meet the other safe harbor conditions. Adding a specific goal relating to preventive items and services also effectuates a change discussed above, in section III.B.6.e.i, in which we removed the reference to preventive items, goods, or services that had appeared in proposed paragraph 1001.952(hh)(3)(i). Furthermore, we note that this change is consistent with section 1128A(i)(6)(D) of the Act, which excepts certain remuneration given to individuals to promote the delivery of preventive care from the definition of ''remuneration'' for purposes of the Beneficiary Inducements CMP, as further interpreted in the regulatory exception at paragraph 1003.101.

l. Prohibition on Cost-Shifting

Summary of OIG Proposed Rule: We sought comments on whether the final rule should include a safe harbor condition that would prohibit VBE participants that furnish patient engagement tools and supports from: (i) Billing Federal health care programs, other payors, or individuals for those tools or supports; (ii) claiming the value of a tool or support as a bad debt for payment purposes under a Federal health care program; or (iii) otherwise shifting the burden of the value of a tool or support on a Federal health care program, other payors, or individuals.

Summary of Final Rule: We are not finalizing this proposed condition.

Comment: Several commenters supported this proposed condition. A commenter agreed that entities offering tools and supports should not receive payment for the value of those items or services, but the commenter asserted that an explicit safe harbor condition prohibiting receiving payment for tools and supports is unnecessary.

Other commenters suggested different variations on this prohibition, urging that any safe harbor condition related to billing for tools and supports should permit entities to bill commercial payors for tools and supports when, for example, a provider has negotiated reimbursement terms that permit certain costs to be passed on to third-party payors. Another commenter urged that OIG prohibit all direct billing of any costs related to protected tools and supports to patients but otherwise allow direct billing for tools and supports to nonpatient third parties. One commenter opposed this cost-shifting prohibition altogether, arguing that because tools and supports could result in overall cost savings to payors, those items and services should be reimbursable.

Response: We are not finalizing this condition. In light of the combination of safeguards in the final rule, we do not believe the addition of a cost-shifting prohibition would add appreciable additional protection for programs or patients. We acknowledge that VBE participants may have a variety of arrangements with payors, including reimbursement terms that permit certain costs to be passed on to third-party payors, and we do not want to foreclose safe harbor protection for such VBE participants. With respect to direct billing of payors or individuals for tools and supports, if the tool or support is a covered item or service under a Federal health care program and a VBE participant appropriately obtains full payment for such tools or supports in accordance with applicable coverage and billing rules, then the VBE participant has not transferred any remuneration to a beneficiary, and the arrangement would not implicate the Federal anti-kickback statute. In other words, if a provider or supplier furnishes items or services that are covered items or services under a Federal health care program, the provision of those items or services alone would not implicate the Federal anti-kickback statute.

However, we would note there could be circumstances under which a VBE participant, when furnishing a covered item or service, does give a Federal

health care program beneficiary something of value, thereby implicating the Federal anti-kickback statute. For example, the Federal anti-kickback statute would be implicated by a provider waiving or reducing any required cost-sharing obligations for the covered item or service incurred by a Federal health care program beneficiary or providing extra items and services—those that are not part of the covered item or service—for free. Furthermore, nothing in this rule exempts parties from responsibility for compliance with all applicable coverage and billing rules. In addition, nothing in this safe harbor transforms an item or service—which is not otherwise billable or allowable under the relevant cost-reporting rules—into a billable or allowable item or service.

Comment: Several commenters warned that the proposed prohibition on billing Federal health care programs would render Indian health care providers ineligible for protection under this new safe harbor because they are federally funded.

Response: As noted, we are not finalizing this condition.

m. No Selection Based on Payor

Summary of OIG Proposed Rule: In the OIG Proposed Rule, we stated that we were considering and solicited comments on whether to include a ''consistent provision'' condition, which would require VBE participants to provide the same patient engagement tools or supports to an entire target patient population or otherwise consistently offer tools or supports to all patients who satisfy specified, uniform criteria.[77] We noted that such condition would protect against a VBE participant targeting certain patients to receive tools and supports based on, for example, the patient's insurance or health status, resulting in targeting of particularly lucrative patients to receive tools and supports (cherry-picking) while avoiding high-cost patients (lemon-dropping). We solicited comments regarding: (i) Whether such a provision would limit certain VBE participants' ability to offer tools and supports due to financial constraints; and (ii) why offering tools and supports to a smaller subset of a target patient population would be appropriate and not elevate fraud and abuse risks, including cherry-picking and lemon-dropping.

Summary of Final Rule: We are finalizing a condition at paragraph 1001.952(hh)(8) that the availability of patient engagement tools and supports cannot be determined in a manner that takes into account the type of insurance coverage of the patient.

Comment: A number of commenters expressed concern that a consistent provision requirement could result in requiring VBE participants to provide tools and supports to an overly broad population, including patients for whom such tools or supports are not clinically appropriate or who do not want the tools or supports. Some commenters posited that VBE participants need flexibility to tailor the types of tools or supports to the particular patient and recommended that we protect remuneration directed at particular subsets or subpopulations of target patient populations of a VBE, such as higher-risk or higher-cost patients, or only those patients within the target patient population who achieve a certain goal. Other commenters suggested that because not all patients within the target patient population may benefit from any tool or support, offerors should be permitted to establish in advance specified criteria by which to evaluate patients for the appropriateness of any tool or support. For instance, a commenter suggested that it would be appropriate to limit the provision of particular tools and supports to subpopulations (*e.g.,* it would be appropriate to exclude patients residing in an assisted living facility who receive significant support with their activities of daily living when furnishing a support such as installing grab bars in patients' homes to prevent falls). A commenter also noted that some patients may refuse tools and supports, which could undermine compliance with a consistent provision requirement.

Response: We acknowledge commenters' concerns regarding the practical challenges of including a consistent provision requirement for safe harbor protection. We have instead adopted a condition that the availability of patient engagement tools and supports cannot be determined in a manner that takes into account the type of insurance coverage of the patient, which largely addresses the concerns that caused us to consider a consistent provision requirement, with fewer practical challenges. Under this condition, VBE participants offering protected tools or supports must do so without regard to the patient's payor type, but nothing in this safe harbor would require a VBE participant to offer tools or supports when they cannot be used or accepted, nor would it require patients to accept unwanted tools or supports in order for the safe harbor to apply. As a practical matter, this condition also would prevent a VBE—assuming at least one VBE participant intends to provide protected tools and supports to patients—from defining its target patient population in a manner that takes into account patients' payor type.

This requirement addresses the concern we expressed in the OIG Proposed Rule related to the possibility of discriminatory provision of tools and supports based on a patient's payor type, but without some of the complications highlighted by commenters, including concerns regarding cost. It is possible that a particular tool or support if offered on a neutral basis unrelated to payor type could result in the provision of tools and supports primarily to Federal health care program beneficiaries. Such remuneration would still be protected under the safe harbor as long as the decision to offer tools and supports was based on a patient's individual need rather than the patient's payor type, and assuming the remuneration otherwise meets the requirements of the safe harbor. More specifically, offering or furnishing tools and supports to patients based on clinical characteristics, such as presence of a specified chronic condition, or geographical considerations, such as a common ZIP Code, would not be precluded even if the patient population receiving the tools and supports disproportionally has the same insurance. By way of further illustration, in the case of a geriatric practice providing tools and supports to patients above a certain age or with a particular illness, it is possible that all or virtually all patients would be Medicare beneficiaries. However, so long as patients receiving the tools and supports are not selected based on their Medicare insurance status, the requirement would not be violated. Stated another way, for purposes of this safe harbor, we would not view a VBE participant offering or furnishing tools and supports to a population disproportionately comprised of Medicare beneficiaries to run afoul of this condition provided that the decision to offer tools or supports is not based upon the patient's Medicare insurance status. As another further example, a VBE could define its target patient population—and therefore limit the scope of potential recipients of tools and supports—based on individual or family income, which might overlap substantially with Medicaid or dual-eligible populations but would not be strictly determined based on an individual's enrollment in Medicaid or as dually eligible for both Medicare and Medicaid.

[77] 84 FR 55729 (Oct. 17, 2019).

This condition ensures that a potential donor uses actual needs or related characteristics outside of payor status to determine the appropriate target patient population rather than the potential value of future Federally reimbursable items and services provided to such population. In addition, nothing in this condition would prevent a VBE participant from offering protected tools and supports only to a population of uninsured individuals, which we would not consider to be a determination based on the type of insurance coverage (indeed, as a preliminary matter, such remuneration would be unlikely to implicate the Federal anti-kickback statute or Beneficiary Inducements CMP).

Comment: A commenter posited that requiring consistent provision across the entire target patient population undercuts the requirement that the tool or support be recommended by the patient's licensed health care practitioner, which includes clinical judgment of the clinician and avoids unnecessary waste and other fraud and abuse concerns. The commenter also noted that VBEs would be forced to create many iterations of the target patient population with minute differences to avoid these concerns, which it described as unfeasible.

Response: We believe the final safe harbor does not raise the risks identified by the commenter because the condition in its final form does not require consistent provision of tools or supports to every patient in an entire target patient population specified by the VBE participant. The final safe harbor also would not require VBE participants to establish different target patient populations merely to satisfy a consistent provision requirement. The commenter is correct that the condition requiring a licensed health care professional's recommendation is designed to preclude from safe harbor protection tools and supports provided to patients who do not need them to advance one of the enumerated goals of this safe harbor.

Comment: Several commenters suggested that providers should have the ability to test the effectiveness of the tool or support before committing to widespread provision, noting that VBE participants are in the best position to make determinations regarding how to allocate limited resources, including whether to offer tools and supports to patients. Other commenters highlighted that small practices may be unable to offer any tools or supports due to financial constraints if they were required to provide them consistently across a population.

Response: We appreciate these comments regarding potential challenges associated with requiring consistent provision of tools and supports across a target patient population. The condition limiting selection based on payor, as finalized, largely accomplishes the goals of a consistent provision requirement without triggering the types of limitations highlighted by these and other commenters. In addition, we agree that VBE participants in collaboration with any applicable VBE are in the best position to make a determination regarding whether to offer and provide a tool or support to patients and emphasize that this determination remains solely at the discretion of a VBE participant (in collaboration with the VBE(s) in which the VBE participant participates).

We are confident the final safe harbor affords VBE participants sufficient flexibility to furnish protected tools and supports and assess their effectiveness, as long as all conditions of the safe harbor are met. For example, a VBE participant may wish to initially establish a narrowly construed target patient population based on specific criteria that limits the size and scope of the patients to whom the VBE participant offers or provides certain tools and supports. After engaging with that limited target patient population, the VBE participant could then identify a new, broader target patient population to whom it offers or provides the same tools and supports. This type of assessment period—and subsequent expansion to a larger, more broadly construed target patient population—could be protected if all conditions of the safe harbor are met, including that the tool or support advances one of the safe harbor's enumerated goals. The requirement to advance one or more of the listed goals means, at a minimum, that the VBE participant reasonably expects the tool or support to be effective in advancing a goal.

We reiterate that safe harbors are voluntary and that this safe harbor does not require any individual or entity to offer free or reduced-cost tools or supports to patients; it sets forth conditions and limitations to ensure safe harbor protection for the provision of such tools or supports. VBE participants are free to evaluate the costs and overall cost savings associated with the provision of patient engagement tools and supports, and to structure such arrangements in economically viable ways as long as such structure does not directly take into account a patient's payor status.

Comment: A commenter supported a prohibition on discriminating based on insurance or payor type to avoid lemon-dropping or cherry-picking.

Response: We appreciate the comment and note that we have adopted a condition designed to prevent lemon-dropping or cherry-picking as it relates to payor type or lack of insurance. In addition, requirements for selecting a target patient population and for involvement of the patient's licensed health care professional provide additional protections against selecting only lucrative patients (cherry-picking) or selectively refusing tools and supports for expensive patients (lemon-dropping).

n. Monitoring Effectiveness

Summary of OIG Proposed Rule: We solicited comments on whether to add a condition requiring offerors to use reasonable efforts to monitor the effectiveness of the tool or support in achieving the intended coordination and management of care for the patient. We also solicited comments on whether to add a safeguard that would require monitoring to ensure that the tool or support does not result in diminished quality of care or patient harm.

Summary of Final Rule: We are not finalizing these conditions because they are not necessary in light of the totality of other conditions we are finalizing in this rule.

Comment: Some commenters supported our proposal to require offerors to use reasonable efforts to monitor: (i) The effectiveness of the tool or support in achieving its intended purpose; and (ii) to ensure the tool or support does not result in diminished care or patient harm. Other commenters opposed this proposal, warning that it would impose an administrative burden that could negatively impact the ability of small, rural, and underserved practices to offer tools and supports. Another commenter noted that it can take a substantial period of time to realize the effects of any intervention and the measurement of these effects often utilize outcome measures that may be unreliable. Some commenters stated that it would be reasonable for the safe harbor to require the offeror of a particular tool or support to document and demonstrate outcomes associated with the tool or support, and monitor use, impact, and quality of such tools and supports. A commenter recommended that if OIG adopts a monitoring requirement, it should allow flexibility to entities in designing a monitoring program in acknowledgment

of the good faith monitoring efforts undertaken.

Response: We acknowledge the concerns raised by commenters, and we are not finalizing a monitoring requirement in this final rule. We note that the safe harbor separately requires that tools and supports must advance one or more of the specific goals articulated at paragraph 1001.952(hh)(3)(vi). Although the final safe harbor does not contain a prospective monitoring requirement, the requirement to advance one or more of the listed goals means, at a minimum, that the VBE participant reasonably expects the tool or support to be effective in advancing a goal.

o. Retrieval of Items and Goods

Summary of OIG Proposed Rule: We solicited comments on whether to include a condition requiring the offeror to make a reasonable effort to retrieve the tool or support in certain circumstances, such as when the patient is no longer in the target patient population or the offeror is no longer a VBE participant. We also solicited comments on whether a minimum value should trigger any retrieval requirement and other issues related to the practicality of retrieval.

Summary of Final Rule: We are not finalizing a retrieval requirement in the final safe harbor.

Comment: Some commenters supported the proposal to require a reasonable effort to retrieve the tool or support if certain conditions are met, such as when the patient is no longer within the target patient population or when the tool or support is valued above a certain threshold (applying appropriate depreciation). Others requested that we clarify that any required retrieval efforts would only need to be reasonable and not hold offerors to unrealistic requirements to retrieve tools or disable software.

One commenter suggested that in order to ensure that an offeror's decision to cease retrieval is not driven by an attempt to inappropriately influence beneficiaries, we could require that decisions regarding whether and how to retrieve items be reviewed and approved by the VBE's accountable body or person responsible for the financial and operational oversight of the VBE.

Other commenters stated that a retrieval requirement would be administratively burdensome, impossible or wasteful for nontransferable consumables, counter to clinical recommendations where a patient still benefits from the tool or support and may prevent potential offerors from providing tools and supports or discourage patients from accepting them. Some commenters noted that the reduced value or obsolescence of the tool or support could render recovery unnecessary, futile, or disproportionate in cost to the value of the tool or support. Another commenter noted that retrieval could be impractical or insensitive following a patient's death and urged us not to finalize the requirement for that reason. Other commenters recommended that if we do finalize this requirement, we include exceptions for patient harm and death and consider only two written attempts at retrieval to be reasonable.

One commenter noted that offerors may have limited legal right to tools and may be unable to retrieve them. Commenters asked us to clarify that if retrieval is not required, offerors still retain the right to recover tools and supports if they deem it reasonable and necessary or otherwise make a business decision to retrieve the tool or support.

Response: We agree with commenters who highlighted the administrative burdens and other challenges associated with any retrieval requirement, and we are not finalizing this requirement. We note, however, that offerors are free to make retrieval efforts or require the return of tools and supports where it would not harm the patient, as long as the decision to retrieve or the extent to which retrieval policies are applied is consistent and not undertaken in a manner that takes into account the volume or value of referrals of Federal health care program business. We further note that the safe harbor separately requires that tools and supports must advance one or more of the specific goals articulated at paragraph 1001.952(hh)(3)(vi). Although the final safe harbor does not contain a retrieval requirement, the requirement to advance one or more of the listed goals means that the VBE participants should cease providing tools or supports they find to be ineffective. In addition, we note that the structure of the safe harbor would necessitate termination of ongoing services (*e.g.,* recurring monthly fees associated with a fitness center membership) if the individual is no longer part of the target patient population or the entity is no longer a VBE participant.

p. Monetary Cap

Summary of OIG Proposed Rule: We proposed a monetary cap on the tools and supports protected under this safe harbor. Specifically, at proposed paragraph 1001.952(hh)(5), we proposed that the aggregate retail value of protected tools or supports furnished to a patient by a VBE participant may not exceed $500 per year unless the tools and supports are furnished to a patient based on a good faith, individualized determination of the patient's financial need. We solicited comments on whether this figure strikes the right balance between: (i) Flexibility for beneficial tools and supports; and (ii) a limit on the amount of protected remuneration to shield patients from being improperly influenced by valuable gifts and to protect Federal health care programs from overutilization or inappropriate utilization. We asked whether $500 was too high or too low, and whether a number of other safeguards or alternatives would be more appropriate.

Summary of Final Rule: We are finalizing, with modifications, an annual $500 monetary cap at paragraph 1001.952(hh)(5). The final rule does not include an exception to the cap requirement that would permit exceeding the monetary cap for patients with demonstrated financial need. Based on public comments, we are including an inflation adjuster.

Comment: Several commenters supported a monetary cap for many reasons, including that it provides a bright-line safeguard for program integrity purposes. Other commenters disagreed with any monetary cap for several reasons, such as finding it unnecessary due to the combination of other proposed conditions or asserting that any monetary cap would be unreasonable because the delivery of care—and tools and supports related to such care—depends on each patient's particular needs. Many commenters supported an exception to the proposed cap based on financial need, while some were concerned with the administrative burden associated with administering a financial need policy, which would require individualized determinations of financial need rather than bright-line limits. A commenter suggested that OIG define financial need using a validated social need screening tool, such as the Hunger Vital Sign, a validated, two-question tool used by health care providers and community-based organizations to identify risk for food insecurity among youth, adolescents, and adults.

Response: We agree with commenters who stated that a monetary cap provides bright-line guidance to VBE participants on the value of acceptable tools and supports. To this end, we are finalizing a straightforward annual, aggregate $500 cap, subject to an inflation adjuster. The final rule does not include the proposed condition that would have allowed the cap to be exceeded, without limitation

on amount, in instances of good faith, individualized determination of a patient's financial need. Because we are not finalizing this condition, we do not need to define financial need.

OIG is mindful that different patients may have different needs and for some patients tools and supports exceeding a retail value of $500 in the aggregate per year could help improve coordination of their care, improve health outcomes, and have other beneficial impacts, particularly for patients with financial need. Nothing in this final rule makes it necessarily unlawful, in individual cases, for a provider or other party to furnish for free or below fair market value tools and supports that exceed $500 per year (nor does this rule make remuneration under $500 automatically immune from sanctions under the Federal anti-kickback statute and Beneficiary Inducements CMP unless it meets all safe harbor conditions). Such arrangements would be evaluated on a case-by-case basis under the statutes, including with respect to the intent of the parties. We note that there may be lawful avenues for providers to offer tools and supports to patients who need tools and supports that exceed an aggregate of $500 annually, particularly those experiencing financial need. For example, the local transportation safe harbor, found at paragraph 1001.952(bb), remains available to protect certain local transportation furnished to patients, provided that the local transportation satisfies the requirements of the safe harbor. With respect specifically to the Beneficiary Inducements CMP, exceptions exist for remuneration that promotes access to care and poses a low risk of harm and for renumeration offered to patients experiencing financial need; the requirements for these exceptions are found at paragraph 1003.110.[78]

In addition, for arrangements involving tools and supports that may exceed the monetary cap, that implicate the Federal anti-kickback statute, Beneficiary Inducements CMP or both, and do not meet any other safe harbor to the Federal anti-kickback statute or exception to the Beneficiary Inducements CMP, the advisory opinion process remains available. OIG has previously issued favorable advisory opinions to health care industry stakeholders seeking to furnish free or below fair market value tools and supports to patients when such tools and supports do not squarely satisfy a safe harbor to the Federal anti-kickback statute, an exception to the Beneficiary Inducements CMP, or both.[79]

Comment: Several commenters asked for clarity regarding how to calculate the ''retail value'' of the tools or supports. A commenter asked OIG to define retail value as the commercial value of the tool or support to the recipient instead of its fair market value. Several commenters agreed that if OIG finalized any cap to the annual aggregate value of protected tools and supports, the cap should apply separately to each VBE participant, rather than at the VBE level or the value-based arrangement level, citing the administrative burden associated with tracking caps for patients receiving tools and supports from different VBE participants. Others suggested that the cap should adjust for inflation over time automatically or through other mechanisms.

Response: The aggregate retail value of patient engagement tools and supports furnished by a VBE participant to a patient may not exceed $500 on an annual basis. The retail value of the tools and supports should be measured at the time they are provided to the patient. Specifically, for purposes of this safe harbor, the retail value is the commercial cost the patient would have incurred at the time the VBE participant provides the tool or support if the patient had procured the tool or support on the open market on their own. We note that, as proposed, this cap applies per VBE participant and per patient, not at the VBE level or the value-based arrangement level. A patient may receive a number of tools and supports from a number of VBE participants (in one or more VBE) through the course of a year, as long as no single VBE participant individually provides more than $500 in aggregate value to the patient per year. The VBE participant providing the tool or support is responsible for tracking the aggregate retail value of the tools or supports that it—and only it—provides to the patient through the course of a year.

VBE participants are not required to monitor the value of tools and supports provided by other parties—even within the same VBE—to a particular patient. This should ease any burden of tracking the value of tools in connection with the aggregate, annual cap. Finally, in response to commenters' suggestions, we are finalizing an annual adjustment to the monetary cap to account for inflation. Under this provision, the monetary cap will be adjusted for inflation to the nearest whole dollar effective January 1 of each calendar year using the Consumer Price Index-Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. OIG will publish an announcement on its website after September 30 of each year reflecting the increase in the CPI–U for the 12-month period ending September 30, and the new monetary cap applicable for the following calendar year.

Comment: A number of commenters suggested increasing the dollar limit of the cap for all tools and supports. Some commenters suggested alternatives, such as per-occurrence limitations on value, coupled with a higher cap. Others proposed increasing the cap or adding additional exceptions to the cap for categories of tools and supports or specific tools and supports such as disposable and nondurable items and supplies; recurring services; ongoing costs for the tool or support (*e.g.,* batteries and software upgrades); transportation; housing and home safety items and services; certain digital or other health-related technologies; home monitoring devices; tools and supports that address chronic or complex disease management; tools and supports for the seriously injured; harm-reduction items (*e.g.,* helmets and medication lockboxes); and other tools and supports that address a patient's social determinants of health. Several commenters asked OIG to consider increasing the cap to account for changes in technology or care innovation over time. Some commenters recommended permitting a higher cap when the VBE's accountable body or responsible person determines the circumstances support it. Others recommended a tiered cap system based on outcomes or on the amount of risk a VBE participant bears.

Response: The generally applicable $500 cap establishes a bright-line limitation for VBE participants seeking protection under this safe harbor. We believe the safe harbor conditions, including the monetary cap, strike an appropriate balance between giving flexibility to VBE participants to provide beneficial tools and supports to

[78] We remind readers that exceptions to the definition of ''remuneration'' under the Beneficiary Inducements CMP apply only for the purposes of the definition of ''remuneration'' applicable to section 1128A of the Act (the Beneficiary Inducements CMP); they do not apply for purposes of section 1128B(b) of the Act (the Federal anti-kickback statute).

[79] *See, e.g.,* OIG, OIG Adv. Op. No. 17–01, *available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-01.pdf* (Mar. 10, 2017) (regarding a hospital system's proposal to provide free or reduced-cost lodging and meals to certain financially needy patients); OIG, OIG Adv. Op. No. 19–03 (Mar. 6, 2019), *available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-03.pdf* (regarding a program offered by a medical center that provides free, in-home followup care to eligible individuals with congestive heart failure and the proposed expansion of this program to include certain individuals with chronic obstructive pulmonary disease).

patients and protecting programs and patients from the improper influence of valuable remuneration. We are not finalizing exceptions to the $500 cap because we believe exceptions would add complexity to this safe harbor and would raise compliance challenges. Further, tools and supports of higher value could improperly influence patients to select treatments or providers not in their best interests, potentially leading to the harms against which the Federal anti-kickback statute is designed to protect.

q. Diversion or Resale

Summary of Proposed Rule: We proposed, at proposed paragraph 1001.952(hh)(4), a condition that would have excluded from safe harbor protection tools or supports if the offeror knew, or should have known, that the tool or support was likely to be diverted, sold, or utilized by the patient other than for the express purpose for which the tool or support was provided.

Summary of Final Rule: We are not finalizing this proposed condition.

Comment: Several commenters supported this condition, while another urged us to consider how such limitation may inadvertently restrict access to these tools. A commenter posited that it is not feasible for a VBE participant to determine the likelihood of diversion and proposed instead limitations on categories of tools and supports that are likely to be abused, such as cell phones. The commenter suggested protection only for tools and supports that are not likely to be abused or those likely to improve health, such as helmets, car seats, and medication lockboxes.

Response: We agree with the commenter who questioned the feasibility of a VBE participant determining the likelihood of diversion. We are not finalizing this provision. Other safeguards we are finalizing in this safe harbor adequately address the concern that a recipient of a tool or support is receiving it for appropriate purposes. For instance, the requirement that a licensed health care professional recommend the tool or support and that it be directly connected to the coordination and management of care should mitigate the risk that a tool or support is likely to be diverted or resold. Similarly, the monetary cap, the requirement that a tool or support advance an enumerated goal, and the restriction on marketing and patient recruitment further limit the risk of diversion or resale.

r. Materials and Records

Summary of Final Rule: We proposed at proposed paragraph 1001.952(hh)(6) that VBE participants providing tools and supports under this safe harbor make available to the Secretary, upon request, all materials and records sufficient to establish that the tool or support was distributed in compliance with the conditions of the safe harbor. We noted that we were considering a requirement that VBE participants retain materials and records sufficient to establish compliance with the safe harbor for a set period of time, such as 6 or 10 years. We did not propose specific parameters regarding the creation or maintenance of documentation in order to allow for flexibility. We solicited comments on several alternative safeguards.

Summary of Final Rule: We are finalizing, with modification, a requirement at paragraph 1001.952(hh)(7) that materials and records sufficient to establish compliance with the safe harbor be made available to the Secretary, including that those records be kept for a period of at least 6 years.

Comment: One commenter stated that a rigid documentation requirement would make clinicians hesitant to use the safe harbor. Another commenter questioned the need for the proposed condition, noting that such documentation is already part of the existing compliance programs. The same commenter further questioned whether OIG would bring an investigation or pursue a Federal anti-kickback case based solely on the failure to satisfy a documentation requirement rather than underlying substantive safeguards. A commenter found documentation—particularly regarding the goals proposed at paragraph 1001.952(hh)(3)(vii)—to be excessive or impractical. Another commenter suggested that it would be appropriate for offerors to retain documentation under this condition for a period of 6 years.

Response: We disagree with the characterization of this documentation requirement as rigid. The condition does not require a signed writing in advance of the provision of tools and supports to a patient, nor does it propose any specific parameters on the type or form of documentation. It simply requires that parties make available, on request, documentation sufficient to show that tools or supports were provided in accordance with the safe harbor's conditions. Safe harbors offer voluntary protection from liability under the Federal anti-kickback statute for specified arrangements, and no entity or individual is required to fit within a safe harbor. Failure to fit within a safe harbor does not mean a party has violated—or even implicated—the Federal anti-kickback statute; it simply means the party may not look to the safe harbor for protection for that arrangement. It would be prudent for any party relying on a safe harbor to protect certain arrangements to document compliance with that safe harbor in some form. For purposes of this safe harbor, we are requiring VBE participants to retain relevant documentation for a minimum of 6 years. This retention period was recommended by a number of commenters and it is consistent with the retention period required by the value-based safe harbors finalized in this rule. In addition, because a 6-year retention requirement is already present in several existing CMS regulations, we expect that many parties are familiar with this retention period and that the maintenance of records is part of their routine business practices.

s. Notice to Patients

Summary of OIG Proposed Rule: We solicited comments on whether to require the VBE to provide a patient receiving a tool or support with written notice identifying the VBE participant and describing the nature and purpose of the tool or support.

Summary of Final Rule: We are not finalizing this requirement.

Comment: A commenter suggested that verbal, not written, notice should suffice. Another commenter stated that if such notice is required, OIG should develop consumer-tested templates to convey the information in an objective, easily understood way that will not mislead beneficiaries or create false expectations or reliance on protected tools and supports. Another commenter objected to any notice requirement as burdensome and questioned whether OIG would use investigative resources based on a claim of deficient notice.

Response: We are not finalizing this requirement. We believe that the appropriate time for the patient to understand the purpose of the tool or support is at the time a licensed health care professional is recommending it for the individual patient. While we are not requiring any formal notice to a patient in this final rule, we expect providers will naturally communicate the purpose of the tool or support to the patient at the time it is recommended in furtherance of the coordination and management of care.

t. Other Comments

Comment: A commenter asked OIG to clarify that its proposed rule does not mean that certain existing or hypothetical practices involving tools and supports to beneficiaries implicate, or constitute violations of, the Federal anti-kickback statute, such as certain group education or certain types of gift cards. Other commenters requested that OIG clarify, in the context of value-based arrangements or otherwise, that the safe harbor protects remote physiologic monitoring tools and services at no or low cost, and furthermore that providing access to software-based platforms for patient-generated health data analytics or telemedicine at no or low cost does not violate the Federal anti-kickback statute.

Response: We decline to provide further guidance related to the various comments summarized above because any analysis of whether any of the various practices and conduct implicate the Federal anti-kickback statute or would be protected by this safe harbor would depend on the facts and circumstances specific to the practice or conduct. We note, however, that the provision of at least some of the tools and supports described above (*e.g.,* tools that facilitate remote monitoring) could be protected by this safe harbor. Parties may seek an OIG advisory opinion for a determination regarding a proposed or existing arrangement.

Comment: A commenter requested clarification regarding the intersection of the proposed safe harbor and the existing safe harbors or exceptions to the definition of ''remuneration'' under the Beneficiary Inducement CMP. Another commenter asked whether an entity is precluded from using the so-called ''promotes access to care exception'' [80] if it becomes a VBE. Furthermore, the commenters asked whether an entity that is a VBE can use both the new safe harbor and the existing exception with the same patients. A commenter asked that we adopt a CMP exception corresponding to the patient engagement and support safe harbor.

Response: The Federal anti-kickback statute and Beneficiary Inducements CMP are separate statutes with separate safe harbors and exceptions, respectively. Any remuneration implicating the Federal anti-kickback statute need only satisfy one safe harbor to be protected under the statute. Similarly, any remuneration implicating the Beneficiary Inducements CMP need only satisfy one exception under that statute to be protected. As a matter of law, arrangements that fit in an anti-kickback safe harbor are also protected under the Beneficiary Inducements CMP.[81] This means that the final safe harbor for patient engagement and support offers protection under the Beneficiary Inducements CMP as well as the Federal anti-kickback statute. The converse is not true, however. Arrangements that fit in an exception to the Beneficiary Inducements CMP are not automatically protected under the anti-kickback safe harbor. A party that is a VBE participant can use any exception under the Beneficiary Inducements CMP for which its arrangement qualifies. In some cases, an arrangement that does not fit in the new safe harbor for patient engagement and support might qualify for protection under the ''promotes access to care exception'' or another CMP exception; this protection would not apply to the anti-kickback statute.

Comment: A commenter noted that this safe harbor does not have a corresponding exception under the physician self-referral law.

Response: The commenter is correct. The physician self-referral law, section 1877 of the Act, does not prohibit remuneration exchanged between physicians or entities and patients, so a corresponding exception would not be necessary.

7. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives (42 CFR 1001.952(ii))

Summary of OIG Proposed Rule: We proposed to create a new safe harbor at paragraph 1001.952(ii) to: (i) Permit remuneration between and among parties to arrangements (*e.g.,* distribution of capitated payments, shared savings or losses distributions) under a model or other initiative being tested or expanded by the Innovation Center under section 1115A of the Act or under the Medicare Shared Savings Program under section 1899 of the Act (collectively ''CMS-sponsored models''); and (ii) permit remuneration in the form of incentives provided by CMS-sponsored model participants and their agents under a CMS-sponsored model to patients covered by the CMS-sponsored model. We proposed certain additional conditions, including a requirement that patient incentives have a direct connection to the patient's health care.

Summary of Final Rule: We are finalizing, with modifications, the safe harbor as proposed at paragraph 1001.952(ii). We are revising the introductory text of paragraphs 1001.952(ii)(1) and (2) to clarify that CMS determines the specific types of financial arrangements and incentives to which safe harbor protection will apply; safe harbor protection will not necessarily apply to every possible financial arrangement or incentive that CMS-sponsored model parties may wish to implement as they participate in the Medicare Shared Savings Program or an Innovation Center model. We are finalizing without substantive change the remainder of proposed paragraph 1001.952(ii)(1) regarding the conditions for safe harbor protection of financial arrangements under a CMS-sponsored model.

We are finalizing with some modification the conditions for safe harbor protection of CMS-sponsored model patient incentives at paragraph 1001.952(ii)(2). First, this final rule specifies at paragraph 1001.952(ii)(2)(ii) that the patient incentive must have a direct connection to the patient's health care unless the participation documentation expressly specifies a different standard, in which case that standard must be met. Second, as explained more fully below, we are moving certain language from the proposed definition of ''CMS-sponsored model patient incentive'' in paragraph 1001.952(ii)(3) to the conditions of safe harbor protection in paragraph 1001.952(ii)(2). Third, we are modifying the safe harbor to provide at paragraph 1001.952(ii)(2)(iii) that an individual other than the CMS-sponsored model participant or its agent may furnish an incentive to a patient under a CMS-sponsored model if that is specified by the participation documentation.

Finally, we are relocating the general substance of the provision that permits patients to retain incentives they received under the CMS-sponsored model from paragraph 1001.952(ii)(2)(v) to new paragraph 1001.952(ii)(4)(iii). We are finalizing the safe harbor definitions at paragraph 1001.952(ii)(3) largely as proposed. As noted above, we are relocating a portion of the definition of ''CMS-sponsored model patient incentive'' to the conditions of safe harbor protection in paragraph 1001.952(ii)(2). In addition, we are clarifying the definition of ''CMS-sponsored model arrangement'' to refer to ''a *financial* arrangement,'' which is consistent with our discussion of the definition in the OIG Proposed Rule.[82] Last, we made two minor technical

[80] Section 1128A(i)(6)(F) of the Act; 42 CFR 1003.110.

[81] A practice permissible under the Federal anti-kickback statute, whether through statutory exception or regulations issued by the Secretary, is also excepted from the Beneficiary Inducements CMP. Section 1128A(i)(6)(B) of the Act.

[82] 84 FR 55731 (Oct. 17, 2019).

revisions to the definition of ''CMS-sponsored model party.''

We are addressing the duration of safe harbor protection at new paragraph 1001.952(ii)(4). We are making a technical edit to the introductory language in proposed paragraph 1001.952(ii)(2) to replace the phrase ''if all of the conditions of paragraph (ii)(2)(i) through (v) are met of this section'' with ''if all of the following conditions are met.''

Modifications to the scope of the safe harbor, conditions of protection, and its duration are summarized and explained in the preamble sections that follow.

a. General Comments

Comment: We received several comments that generally supported finalizing a safe harbor for CMS-sponsored models and agreed with the goals set forth in the OIG Proposed Rule. For example, a commenter posited that the safe harbor could encourage greater voluntary participation in new CMS-sponsored models. Commenters also expressed support for a simplified and standardized approach rather than disparate OIG waivers, with tailored conditions, for CMS-sponsored models.

Some commenters expressed concern about the impact of any safe harbor on existing waivers of the fraud and abuse laws issued by OIG that currently apply to CMS-sponsored models, and about our ability or willingness to issue future waivers. For example, a commenter noted that there are benefits to model-specific waivers that may not be realized in a safe harbor.

Response: A goal of this safe harbor is to provide uniformity and predictability for those participating in CMS-sponsored models, which are testing innovations to improve quality and lower cost. As we stated in the OIG Proposed Rule, this safe harbor does not supersede OIG's existing fraud and abuse waivers for CMS-sponsored models. Existing model waivers will continue in effect in accordance with the waiver terms. A CMS-sponsored model party may structure arrangements that might otherwise implicate the Federal anti-kickback statute, Beneficiary Inducements CMP, or both to meet the terms of an applicable fraud and abuse waiver or any applicable safe harbor. In addition, the promulgation of this safe harbor does not preclude OIG from issuing model-specific waivers in the future. We note, however, that we would expect OIG's issuance of model-specific waivers in the future to be infrequent. We expect that model participants in new CMS-sponsored models will be able to use this new safe harbor.

b. Scope of the Safe Harbor and Definitions

Summary of OIG Proposed Rule: We proposed to create a new safe harbor at paragraph 1001.952(ii) to protect certain financial arrangements and patient incentives related to the Medicare Shared Savings Program under section 1899 of the Act and models established and tested by CMS under section 1115A of the Act. At proposed paragraph 1001.952(ii)(3), we proposed to define the following terms that shape the scope of the safe harbor: ''CMS-sponsored model, ''CMS-sponsored model arrangement,'' ''CMS-sponsored model participant,'' ''CMS-sponsored model party,'' ''CMS-sponsored model patient incentive,'' and ''participation documentation.''

Summary of Final Rule: We are finalizing, with modifications, the defined terms. We have modified the definition of ''participation documentation'' by removing the phrase ''is currently in effect.'' This phrase is unnecessary in the context of a definition. Temporal language is more appropriate in the new paragraph 1001.952(ii)(4) that specifies the duration of safe harbor protection. In addition, we have modified the definition of ''participation documentation'' by replacing the reference to ''cooperative agreement'' with the phrase ''legal instrument setting forth the terms and conditions of a grant or cooperative agreement.'' The purpose of this change is to accommodate future CMS-sponsored models that may be implemented by a type of grant that is not a cooperative agreement and to accurately characterize the relevant documentation for such forms of Federal funding.

Comment: We received several comments recommending that we expand the safe harbor beyond ''CMS-sponsored models,'' as we proposed to define that term. For example, some commenters requested protection for arrangements and patient incentives related to other waivers, demonstrations, value-based arrangements, and commercial payors such as: (i) Arrangements under State Innovation Waivers granted pursuant to section 1332 of the Affordable Care Act; (ii) arrangements involving commercially insured patients that operate ''alongside'' an arrangement related to the CMS-sponsored model if the commercial arrangement is identical in all respects to the CMS-sponsored model arrangement; (iii) arrangements needed to support CMS-approved Medicaid Alternative Payment Models and delivery system initiatives; (iv) arrangements established in the Medicare Physician Fee Schedule and Merit-based Incentive Payment System (MIPS); and (v) arrangements between organizations participating in any CMS-led or CMS-supported demonstration authorized by statute.

Some commenters also sought to have the safe harbor protect tools and supports furnished to patients who are: (i) Approved by CMS through a Medicaid section 1115 waiver; (ii) approved by CMS as a State Plan Amendment; or (iii) allowed through Supplemental Benefit for Chronically Ill Enrollees in the Medicare Advantage program. Another commenter recommended that the safe harbor protect arrangements under any model where the Secretary has sufficient authority to waive the Federal fraud and abuse laws.

In contrast, we received support for limiting the scope of protection to what we set forth in the OIG Proposed Rule, with some commenters opposing broadening the safe harbor to protect remuneration for models or demonstrations under other sections of the Act. For example, a commenter opposed broadening the scope of the safe harbor, suggesting that it is appropriate for the Federal anti-kickback statute to serve as ''backstop.''

Response: We have carefully considered the comments requesting expansion of this safe harbor beyond CMS-sponsored models, as that term is as defined in the OIG Proposed Rule. We are finalizing the scope of the safe harbor as proposed. This safe harbor is designed to work in tandem with the Innovation Center's models under section 1115A of the Act and the Medicare Shared Savings Program under section 1899 of the Act. It permits a certain amount of flexibility, which is sufficiently low risk because CMS includes program integrity safeguards in the Medicare Shared Savings Program and the Innovation Center models. There may be variation in program integrity safeguards and oversight in other initiatives, even if the authorizing statute permits the waiver of fraud and abuse laws.

We are tailoring the scope of the safe harbor to include the Medicare Shared Savings Program under section 1899 of the Act and models established and tested by CMS under sections 1115A and of the Act. Both the Medicare Shared Savings Program and Innovation Center models are: (i) Designed to coordinate and redesign care; and (ii) contain program integrity oversight and safeguards. In addition, the Innovation Center oversees the development, testing, and monitoring of models.

Furthermore, CMS-sponsored model participants may undergo certain screening to participate in a model or the Medicare Shared Savings Program and may be subject to documentation and reporting requirements to promote transparency in the model or program. This level of CMS involvement and oversight may not be present in many of the programs, waivers, and demonstrations cited by the commenters. To the extent that the Department has the authority to issue fraud and abuse waivers for the Medicare Shared Savings Program or Innovation Center models, the issuance of any such waivers remains an option to protect certain arrangements in those programs. In addition, other safe harbors may protect many arrangements that may otherwise implicate the Federal anti-kickback statute and Beneficiary Inducements CMP, and that participants in the types of programs described above may desire to implement.

Comment: A commenter asked that this safe harbor protect a broad range of incentives given to patients such as transportation, nutrition support, home monitoring technology, and gift cards.

Response: This safe harbor protects patient incentives for which CMS has determined that this safe harbor is available. Thus, CMS defines in the participation documentation the scope of the model or program and the arrangements or incentives permitted under the model or program. Depending on the particular CMS-sponsored model's parameters, the safe harbor could protect a broad range of incentives, including those cited by the commenter. If the CMS-sponsored model prohibits a particular type of incentive, then it would not be protected by this safe harbor. Similarly, we note that CMS defines which entities may provide an incentive. For example, if the CMS-sponsored model is a State-based model where the State or State Medicaid agency implements the model through care-delivery partners in a State, the Innovation Center may expressly specify that such State partners may provide CMS-sponsored model patient incentives under the model on behalf of the State.

We are modifying the proposed definition of ''CMS-sponsored model patient incentive'' at paragraph 1001.952(ii)(3)(v) for simplicity and to consolidate at paragraph 1001.952(ii)(2) language regarding the conditions of safe harbor protection.

We proposed to define ''CMS-sponsored model patient incentive'' to mean remuneration not of a type prohibited by the participation documentation and is furnished consistent with the CMS-sponsored model by a CMS-sponsored model participant (or by an agent of the CMS-sponsored model participant under the CMS-sponsored model participant's direction and control) directly to a patient under the CMS-sponsored model. We are moving the phrase ''furnished consistent with the CMS-sponsored model'' to paragraph 1001.952(2)(v), and we are moving the requirement regarding who may furnish the patient incentive to paragraph 1001.952(2)(iii). We are relocating the language so it will appear where the other conditions for patient incentives are enumerated under paragraph 1001.952(ii)(2), rather than including these requirements within the definition of ''CMS-sponsored model patient incentive.'' We do not intend for this to be a substantive change.

Comment: A commenter recommended expanding the safe harbor to include incentives given to patients who the CMS-sponsored model participant believes in good faith are covered, or within a reasonable period will be covered, by a CMS-sponsored model. The commenter noted as an example that the Comprehensive ESRD Care Model has shown that 120 or more days may elapse between the time when a Medicare beneficiary commences dialysis treatment and the time by which the ESRD Seamless Care Organization receives confirmation of beneficiary alignment.

Response: As with the scope of permissible types of incentives, the Innovation Center defines the scope of patients who may be eligible to receive such incentives. We recognize that, depending on how the Innovation Center has designed the model, a CMS-sponsored model participant may not know exactly which beneficiaries are in the model or aligned to the model participant at the time the beneficiary could benefit from a patient incentive. By definition, a ''CMS-sponsored model patient incentive'' is remuneration that is not of a type that is prohibited by the participation documentation. Also, as a condition of safe harbor protection, the incentive must be furnished consistent with the CMS-sponsored model. To the extent that the Innovation Center intends for incentives to be furnished before any beneficiary alignment is finalized, and the participation documentation or programmatic requirements do not prohibit such incentives, an incentive given before final alignment could still meet the condition set forth in paragraph 1001.952(ii)(2)(v) and qualify for safe harbor protection if all other terms of the safe harbor are met.

Comment: A commenter noted that we proposed to define ''CMS-sponsored model'' to include a model expanded under section 1115A(c) of the Act and requested further clarity on how this safe harbor would apply to ''Phase II'' testing of an Innovation Center model. The commenter noted that risks and benefits of financial arrangements and patient incentives under a model may change within a given model's design due to a change in scope.

Response: The safe harbor would protect arrangements and incentives consistent with the CMS-sponsored model regardless of the model's phase of testing. We agree with the commenter that risks and benefits of financial arrangements and patient incentives under such models may change, but the Innovation Center would continue to set the parameters of what is being tested. If a CMS-sponsored model participant's arrangements or incentives meet the terms of the safe harbor, which incorporates elements of the model design, then the arrangements or incentives would be protected.

c. Conditions for Safe Harbor Protection

Summary of OIG Proposed Rule: We proposed safeguards to ensure that arrangements protected by this safe harbor operate as intended by CMS, including requirements that: The remuneration not induce the furnishing of medically unnecessary services or reduce or limit medically necessary care (proposed at paragraph 1001.952(ii)(1)(ii)); the remuneration not induce referrals of patients outside the CMS-sponsored model (proposed at paragraph 1001.952(ii)(1)(iii)); the parties make materials and records available to the Secretary upon request (proposed at paragraphs 1001.952(ii)(1)(v) and 1001.952(ii)(2)(iii)); the parties satisfy programmatic requirements imposed by CMS (proposed at paragraphs 1001.952(ii)(1)(vi) and 1001.952(ii)(2)(iv)); and a patient incentive offered under the safe harbor have a direct connection to patient care (proposed at paragraph 1001.952(ii)(2)(ii)).

Summary of Final Rule: We are finalizing, with modifications, the conditions of this safe harbor. Specifically, paragraph 1001.952(ii)(2)(ii) is finalized with a modification to provide that the CMS-sponsored model patient incentive must have a direct connection to the patient's health care, unless the participation documentation specifies a different standard. We are liberalizing and relocating to paragraph 1001.952(ii)(2)(iii) language regarding

who may furnish a CMS-sponsored model patient incentive. Specifically, a CMS-sponsored model patient incentive must be furnished by a CMS-sponsored model participant (or by an agent of the CMS-sponsored model participant under the CMS-sponsored model participant's direction and control), unless otherwise specified by the participation documentation. We also are moving to paragraph 1001.952(ii)(2)(v) the proposed language specifying that a CMS-sponsored model patient incentive must be ''furnished consistent with the CMS-sponsored model.'' As proposed, the relocated provisions were essentially conditions of safe harbor protection. To improve the clarity of the final rule, we are moving the provisions to appear with the other conditions for protecting CMS-sponsored model patient incentives.

Comment: A commenter suggested that safe harbor protection should apply as long as the remuneration at issue meets all programmatic requirements and the terms of the model participation agreements or other participation documentation. The commenter expressed concern that incorporating additional substantive requirements in the safe harbor beyond the model's contractual and programmatic requirements could: (i) Limit the ability to tailor program integrity requirements for specific models; and (ii) potentially lead to inconsistent or conflicting formulations of similar concepts such as between the safe harbor and the model's contractual and programmatic requirements. The commenter illustrated this concern by explaining that the Innovation Center may test a model that allows for the provision of patient incentives that have no direct connection to the patient's health care and instead includes a different safeguard. Another commenter, while supporting the all-encompassing approach to the safe harbor, stated that the specific requirements regarding protected parties are redundant because they are already currently embedded within most of the Innovation Center model participation requirements. Another commenter urged OIG to look carefully at the safe harbor conditions and modify any conditions that impose an undue burden or that are unclear.

Response: We appreciate the desire to streamline the safe harbor's conditions as much as possible. However, if we were to add a condition requiring satisfaction of *all* programmatic requirements and *all* terms of the model participation agreements and other participation documentation to ensure safe harbor protection, then some arrangements or incentives might not be protected due to potentially inadvertent failures to satisfy model requirements that may not bear on the particular financial arrangement or patient incentive. We recognize that implementing a safe harbor rather than continuing with model-by-model fraud and abuse waivers may result in an approach less tailored to the specific model. Similarly, in an effort to encompass an array of possible models, we may have introduced some redundancy through defined terms or safe harbor conditions that also could appear in programmatic requirements for a particular CMS-sponsored model. However, we believe the benefits of having a safe harbor available that provides consistency and certainty to parties considering participation in a CMS-sponsored model outweigh the concerns related to any possible redundancy.

The conditions we are finalizing generally either rely on parameters CMS will specify as part of the CMS-sponsored model or address important program integrity concerns and resemble conditions previously included in model-specific waivers (*e.g.,* the condition prohibiting parties from offering, paying, soliciting, or receiving remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of the CMS-sponsored model). CMS defines the parameters of the model, which includes the types of financial arrangements and incentives that could receive safe harbor protection. Finally, as we noted in the OIG Proposed Rule, the condition requiring that the patient incentive have a direct connection to the patient's health care is consistent with the design of all CMS-sponsored models contemplated as part of this safe harbor.

However, to provide additional flexibility for the Innovation Center to design future models and in response to commenters, we are modifying the condition such that CMS may specify in the participation documentation a standard other than ''direct connection to the patient's health care.'' If CMS does not specify a particular standard that would contrast with a ''direct connection to the patient's health care,'' then this standard remains. In other words, if CMS does not specify any particular standard to which the incentive must relate, then the standard is that it must directly relate to the patient's health care. If, for example, a CMS-sponsored model permitted incentives related to social determinants that might not ''directly'' relate to a patient's health, and the participation documentation specified that the incentive must bear a ''reasonable'' connection to the patient's health, then compliance with the ''reasonable connection'' standard would satisfy the safe harbor condition.

As we stated in the OIG Proposed Rule, to reduce administrative burden, parties under a CMS-sponsored model would have flexibility to determine which type of documentation would best memorialize the arrangement such that they could demonstrate safe harbor compliance, including through a collection of documents as opposed to one agreement.[83]

Comment: A commenter expressed concern that the safe harbor condition requiring an arrangement to satisfy ''other programmatic requirements'' would leave the protection for these arrangements significantly uncertain.

Response: The regulatory text that we proposed and are finalizing requires that the CMS-sponsored model participant satisfies (or CMS-sponsored model parties satisfy) such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor. The phrase ''other programmatic requirements'' appeared in the preamble of the OIG Proposed Rule[84] and needed to be considered in the context of the totality of the condition. The programmatic requirements that parties would have to satisfy to qualify for safe harbor protection would be set out in the CMS-sponsored model's participation documentation or would be otherwise publicly available. Therefore, we disagree with the commenter that the protection would be uncertain, since any programmatic requirements specified by the Innovation Center and incorporated into the safe harbor by reference in this condition would be in participation documentation or otherwise would be publicly available.

Comment: A commenter recommended that OIG specify that the safe harbor is automatically applicable to CMS-sponsored models absent any affirmative exclusion of a CMS-sponsored model from protection by the safe harbor by OIG, rather than requiring the Innovation Center to specify that the safe harbor applies to a particular model.

Response: We did not propose and are not adopting this recommendation because safe harbor protection may not be necessary to test all models or for every arrangement within a model that the Innovation Center may test under section 1115A of the Act. This approach

[83] 84 FR 55732 (Oct. 17, 2019).

[84] *Id.*

allows the Innovation Center to evaluate each model and determine whether waivers are necessary for parties to enter into certain arrangements to effectuate the purposes of the particular model. CMS has broad authority to develop and define the Innovation Center models, what the models are testing, and the scope of participation in the models. It is important, therefore, that CMS affirmatively state that the safe harbor would be available for specific CMS-sponsored model arrangements and CMS-sponsored model patient incentives within a particular model or initiative. As we stated in the OIG Proposed Rule, CMS would determine whether the safe harbor protection would be available for arrangements or patient incentives under the particular CMS-sponsored model.[85] We also explained that we would expect CMS to notify CMS-sponsored model participants, through participation documentation, or other public means as determined by CMS, when CMS-sponsored model participants may use this safe harbor under a CMS-sponsored model.[86] To ensure that it is clear that CMS determines the arrangements or incentives (and not just the models, in general) for which safe harbor protection is available, this final rule makes a technical correction to the proposed regulatory text to remove ''in a model'' in paragraph 1001.952(ii)(1) and ''under a model'' in paragraph 1001.952(ii)(2).

Because this safe harbor was not available when existing models began, we recognize that the applicable participation documentation would not affirmatively reference that this safe harbor is available for particular arrangements or incentives as required by paragraphs 1001.952(ii)(1) and (2). Consequently, we clarify that for the Medicare Shared Savings Program and any existing model that has a fraud and abuse waiver issued by OIG, CMS may determine that this safe harbor is available for specific CMS-sponsored model arrangements and CMS-sponsored model patient incentives that began prior to issuance of this final rule. To do so, CMS would at its discretion issue a public notice or notice to individual CMS-sponsored model participants that such parties can seek protection for such arrangements under this safe harbor as of the effective date of that notice. For example, if a particular CMS-sponsored model has a waiver for patient engagement incentives, the parties may rely either on the fraud and abuse waiver or, following notice from CMS that this safe harbor may be available for protection of future incentives, this safe harbor provided all of the waiver's or safe harbor's conditions, as applicable, are met.

d. Duration

Summary of OIG Proposed Rule: We proposed that the duration of safe harbor protection would align with the duration of the participation documentation under a CMS-sponsored model, including a period of time after that model ends to allow for reconciliation.[87] We indicated that we might finalize one or a combination of the following options: (i) Terminating protection after the end of the performance period or within a certain time period after the end of a performance period; (ii) terminating protection upon termination of the CMS-sponsored model participation documentation or within a certain period of time after that; and (iii) terminating protection after the last payment or exchange of anything of value made by a CMS-sponsored model party under a CMS-sponsored model occurs, even if the model has otherwise terminated. We also solicited comments on whether a CMS-sponsored model participant should be able to continue to provide the outstanding portion of any service to a patient if the service was initiated before its participation documentation terminated or expired.

Summary of Final Rule: We are adding a new paragraph 1001.952(ii)(4) that specifies timeframes for when safe harbor protection begins and ends. The details of each timeframe are explained in greater detail below.

Comment: While generally agreeing with our proposal that most safe harbor protections should end at the conclusion of the model, a commenter suggested that there are some instances when OIG should consider extended safe harbor protection for CMS-sponsored model patient incentives. For example, a commenter recommended that OIG continue safe harbor protection if ceasing protection would affect continuity of care for patients or if the protected incentives promoted positive outcomes for the patient. Similarly, another commenter recommended that patients be allowed to retain any incentives received prior to the termination or expiration of the participation documentation of the CMS-sponsored model participant. Furthermore, the commenter also recommended protecting participants who continue to provide the same service to a patient for a terminated model if the service was initiated before the model was terminated or expired.

Response: We agree with commenters, in part. The proposed regulatory text at paragraph 1001.952(ii)(2)(v) stated that patients would be permitted to retain any incentives received prior to the termination or expiration of the participation documentation of the CMS-sponsored model participant. We are finalizing that proposed provision in this final rule, but it is now included in paragraph 1001.952(ii)(4)(iii).

We also agree that there are circumstances where it may be appropriate to continue protection for patient incentives given after the date on which the model concludes. However, this safe harbor protects only patient incentives that are furnished consistent with the CMS-sponsored model. In the OIG fraud and abuse waiver context, we have protected patient incentives that continued past expiration or termination of an agreement for a certain period of time. For example, in connection with the Bundled Payments for Care Improvement (BPCI) Advanced Model, we indicated that the waiver for beneficiary incentives would continue to apply for patients who were in a ''clinical episode'' that began during an ''Agreement Performance Period,'' as those terms were defined in the Participation Agreement for that particular model, recognizing that the clinical episode might not conclude before the end of the Agreement Performance Period.[88] However, not all models may be tied to particular clinical episodes. If a model ends, or a particular CMS-sponsored model participant's participation documentation terminates, the safe harbor would not protect patient incentives indefinitely, even if the incentive benefits or improves outcomes for a particular patient. More specifically, we are providing at new paragraph 1001.952(ii)(4)(iii) that safe harbor protection would continue for incentives given on or after the first day on which patient care services may be furnished under the CMS-sponsored model as specified by CMS in the

[85] 84 FR 55731 (Oct. 17, 2019).

[86] *Id.*

[87] Specifically, the OIG Proposed Rule stated that the ''safe harbor would protect the last payment or exchange of value made by or received by a CMS-sponsored model party following the final performance period that the CMS-sponsored model participant that is a party to the arrangement participates in the CMS-sponsored model.'' 84 FR 55733 (Oct. 17, 2019).

[88] *See* Notice of Amended Waivers of Certain Fraud and Abuse Laws in Connection With the Bundled Payments for Care Improvement Advanced Model (Jan. 1, 2020), *available at https://www.cms.gov/files/document/notice-amended-waivers-certain-fraud-and-abuse-laws-connection-bundled-payments-care-improvement.pdf.*

participation documentation and no later than the last day on which patient care services may be furnished under the CMS-sponsored model, unless a different timeframe is established in the participation documentation (*e.g.,* a clinical episode if such a concept is incorporated into a model). Thus, if the participation documentation expressly specifies a period of time beyond the end of a final performance period or other termination event during which a CMS-sponsored model patient incentive may be given, then that incentive would be protected during that extended timeframe, assuming all other safe harbor conditions are met. If the participation documentation does not specify an extended timeframe, then this safe harbor protects only incentives furnished until the last day on which patient care services may be furnished under the CMS-sponsored model (*e.g.,* the last day of the final performance period). In addition, for clarity, we are specifying that protection for CMS-sponsored model patient incentives begins on or after the first day on which patient care services may be furnished under the CMS-sponsored model as specified by CMS in the participation documentation. In general, this would be the first day of the first performance period during the model.

This approach is generally consistent with timeframes incorporated into fraud and abuse waivers for existing models. We further note that some arrangements that cease to meet the requirements of this safe harbor could be structured to fit into the safe harbor for patient engagement and support at paragraph 1001.952(hh).

Comment: With respect to CMS-sponsored model arrangements, a commenter recommended that the safe harbor protect the last payment or exchange of value made or received by a CMS-sponsored model party following the final performance period in which the CMS-sponsored model participant that is a party to the arrangement participates, even if the model has otherwise terminated.

Response: We agree, and it was our intent in the OIG Proposed Rule that the safe harbor protect remuneration exchanged pursuant to CMS-sponsored model arrangements for a limited period of time after the CMS-sponsored model expires or is terminated to allow for necessary reconciliation. We are addressing the duration of safe harbor protection in new paragraph 1001.952(ii)(4), which provides greater clarity than addressing the issue in certain defined terms. We address both the start date and end date for protection in a manner that aligns with the particular CMS-sponsored model. The start or end date for protection may differ depending on whether the CMS-sponsored model is governed by participation documentation in the form of a legal instrument setting forth the terms and conditions of a grant or a cooperative agreement. For remuneration provided in connection with arrangements under a CMS-sponsored model governed by participation documentation other than a legal instrument setting forth the terms and conditions of a grant or cooperative agreement, the safe harbor protects the exchange of remuneration between CMS-sponsored model parties that occurs on or after the first day on which services under the CMS-sponsored model begin and no later than six months after the final payment determination made by CMS. The first day on which services begin is often the first day of the first performance period of a model, which may be referred to in the participation documentation as the ''Start Date.'' If a CMS-sponsored model has an ''implementation period'' included in the participation documentation, the first day on which ''services under the CMS-sponsored model begin'' would be the first day of the implementation period, unless otherwise specified by CMS in the participation documentation. For a CMS-sponsored model governed by a legal instrument setting forth the terms and conditions of a grant or cooperative agreement, the safe harbor protects the exchange of remuneration between CMS-sponsored model parties that occurs on or after the first day of the period of performance (as defined at 45 CFR 75.2), which is specified in the Notice of Award, or such other date specified in the participation documentation and no later than six months after closeout occurs pursuant to 45 CFR 75.381.

We emphasize, however, that the safe harbor protects only remuneration between or among CMS-sponsored model parties under a CMS-sponsored model arrangement for which CMS has determined that this safe harbor is available, and that a ''CMS-sponsored model arrangement'' includes only ''a financial arrangement between or among CMS-sponsored model parties to engage in activities under the CMS-sponsored model . . . .'' Therefore, the safe harbor does not protect remuneration exchanged between CMS-sponsored model parties for activities such as care coordination or other patient-care activities that occur before the model begins or beyond the termination or expiration of the model. Any such activities that are undertaken after the model expires or is terminated are not ''activities under the model.''[89] Payment that is made within the specified timeframe in paragraph 1001.952(ii)(4)(i) or (ii) for such services that were completed prior to termination or expiration of the final model performance period can be protected, similar to reconciliation payments that would necessarily be completed after expiration or termination of the final model performance period. In addition, CMS may specify that no remuneration may be exchanged after termination of the participation documentation if a participant is terminated from the CMS-sponsored model for cause. Any such remuneration would be prohibited by the model and thus not protected by the safe harbor. We also recognize that some CMS-sponsored model participants might want protection for certain arrangements that begin before a model starts (''pre-participation''). This safe harbor protects only financial arrangements among, and patient incentives furnished by, parties participating in the CMS-sponsored model. Any pre-participation arrangements not governed by participation documentation (in contrast to arrangements in an implementation period that is part of a CMS-sponsored model, as explained above) would need to comply with existing law, including another safe harbor, or CMS could request a fraud and abuse waiver be issued to cover activities in the pre-participation time period.

8. Cybersecurity Technology and Related Services (42 CFR 1001.952(jj))

Summary of OIG Proposed Rule: We proposed to establish a new safe harbor at paragraph 1001.952(jj) to protect nonmonetary donations of certain cybersecurity technology and related services to help improve the cybersecurity posture of the health care industry. We proposed to define ''cybersecurity'' as the process of protecting information by preventing, detecting, and responding to cyberattacks, and we proposed to include within the scope of covered technology any software or other types of information technology, other than hardware. In an effort to foster

[89] In contrast, some CMS-sponsored models may require various administrative or analytical services that can occur only after a model terminates or expires (*e.g.,* data or financial analysis, including services related to the reconciliation process). Remuneration related to those required activities, which would be described in the participation documentation, would be protected by this safe harbor, if all conditions are met.

beneficial cybersecurity donation arrangements without permitting arrangements that might negatively impact beneficiaries or Federal health care programs, we proposed a number of conditions on cybersecurity donations protected by the safe harbor. We also included an alternative proposal to protect donations of cybersecurity hardware in more limited circumstances. These proposals are summarized in more detail in following sections of this preamble.

Summary of Final Rule: We are finalizing, with modifications, the safe harbor at paragraph 1001.952(jj). The modifications are summarized in more detail in following sections. This safe harbor will protect arrangements intended to address the growing threat of cyberattacks impacting the health care ecosystem. In addition to software and other types of information technology, the final safe harbor will protect certain cybersecurity hardware donations that meet conditions in the safe harbor. We are not finalizing our alternative proposal to require parties to conduct a risk assessment prior to donating hardware.

a. General Comments

Comment: Most commenters generally supported OIG's proposed cybersecurity technology and related services safe harbor, with several commenters supporting the safe harbor as proposed. Some commenters highlighted that patients and providers of all sizes benefit when small and under-resourced providers can better protect themselves against cybersecurity threats. For example, a commenter stated that the safe harbor would significantly benefit small and rural provider groups that lack the required resources to install needed cybersecurity measures. Another commenter stated that four in five physicians in the United States currently have experienced some form of cybersecurity attack compromising patient privacy.[90] According to a commenter, with the growing cost of cybersecurity software, it is essential that stakeholders be able to donate cybersecurity software to entities with which they interact that may not be able to afford the software. This commenter highlighted the threat that infiltrated data systems could lead to the corruption of health records, while another commenter explained that patient safety is the most critical concern when cyberattacks occur, especially when they impact a patient's electronic health records or medical devices. At least one of these commenters noted that cyberattacks could result in disclosure of sensitive patient information and could alter the treatment that a patient is prescribed, among other negative consequences.

Response: We agree that there is an urgent need to improve cybersecurity hygiene in the health care industry to protect patients and the health care ecosystem overall. As discussed in more detail below, we are finalizing the safe harbor, with several modifications.

Comment: A small number of commenters expressed general concerns about the proposal. One commenter warned that the safe harbor should not be used to further intentional or unintentional anticompetitive behavior, while another commenter stated that a safe harbor of this kind is bound to be abused, regardless of the types of safeguards OIG implements. Another commenter asked OIG to reconsider this safe harbor and whether cybersecurity protection and any donations related to the same are understood sufficiently at this time to warrant a safe harbor.

Response: While we appreciate the concerns expressed by these commenters, we believe that this safe harbor can be an important tool to help the health care industry address the prevalent and increasing cybersecurity threats facing the industry, which can negatively impact the quality of care delivered to beneficiaries, among other things.[91] Any donation of valuable technology or services to physicians or other sources of Federal health care program referrals may pose the risk of harms associated with fraud and abuse, and such risk may increase as the value of the donated technology or services increases. Similarly, any time a health care industry stakeholder is permitted to give something for free or at a reduced cost to actual or potential referral sources, there is a risk that such donation or discount will affect competition because entities with greater financial resources may be in a better position to provide the donation or discount or a more valuable donation or discount. However, we believe that the combination of safeguards in the safe harbor, as finalized, appropriately balances the risks against the potential benefits of properly structured donations to help address the critical cybersecurity needs of the health care industry.

b. Purpose of Donation

Summary of OIG Proposed Rule: We proposed in proposed paragraph 1001.952(jj)(1) to limit safe harbor protection to donated technology and services that are necessary and used predominantly to implement and maintain effective cybersecurity. We solicited comments on the breadth of protected technology and services, particularly surrounding multifunctional technologies and services that might have use or value to a recipient beyond implementing and maintaining effective cybersecurity, such as donations that are otherwise used in the normal course of a recipient's business, which we did not propose to protect.

Summary of Final Rule: We are finalizing, with modifications, our proposal to limit the applicability of the cybersecurity safe harbor to technology and services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. However, in the final cybersecurity safe harbor as established here, this limitation will be placed in the introductory paragraph of 1001.952(jj), instead of a condition in 1001.952(jj)(1). (The remaining conditions of the safe harbor will be finalized with redesignated numbering to account for this organizational change; for example, proposed paragraph 1001.952(jj)(2)(i) will be finalized at paragraph 1001.952(jj)(1)(i), and so forth). We are also removing the phrase ''certain types of'' before ''cybersecurity technology and services'' from the introductory paragraph to avoid ambiguity regarding the scope of the safe harbor. As finalized, the cybersecurity safe harbor introductory paragraph will read as follows: As used in section 1128B of the Act, 'remuneration' does not include nonmonetary remuneration (consisting of cybersecurity technology and services) that is necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity, if all of the conditions in paragraphs (jj)(1) through (4) of this section are met.

This organizational change does not alter the scope of remuneration protected by the safe harbor. This reorganization of the final cybersecurity safe harbor is intended to ensure consistency with the EHR safe harbor, without altering or affecting the substance of the ''necessary and used predominantly'' standard as discussed in the proposed rule. As finalized, the introductory paragraph of the

[90] *See* Healthcare and Public Health Sector Coordinating Councils, *Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients, available at https://www.phe.gov/Preparedness/planning/405d/Documents/HICP-Main-508.pdf.*

[91] *See for example* Health Care Industry Cybersecurity Task Force, *Report on Improving Cybersecurity in the Health Care Industry,* June 2017 (HCIC Task Force Report), *available at https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf* (recommending safe harbor protection for cybersecurity donations).

cybersecurity safe harbor mirrors the introductory paragraph in the EHR safe harbor at paragraph 1001.952(y), which provides that donated items or services must be necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records. We believe this consistency is especially important insofar as certain cybersecurity software may be donated under both safe harbors.

Comment: A number of commenters supported the ''necessary and used predominantly'' standard. A commenter noted that this provision would ensure the legitimacy of donations and help differentiate the technology and services that may have multiple uses beyond cybersecurity. Another commenter urged OIG to require a clear nexus between the cybersecurity donation and the business relationship. The commenter explained that the cybersecurity technology should be necessary for the provision of the services involved, such as when a hospital donates cybersecurity technology to a physician to ensure the secure transfer of personal health information and thus improve care coordination for shared patients. The commenter stated that this safe harbor should not protect cybersecurity technology donations that are used as a way to entice new business.

Response: The goal of this condition is to ensure that donations are made to address the legitimate cybersecurity needs of donors and recipients, not to induce new Federal health care program business. We decline to adopt the ''clear nexus'' standard suggested by the commenter, and we reiterate that the donation must be ''necessary'' under this condition. It is unlikely that a donation would be necessary for the donor or recipient to implement, maintain, or reestablish effective cybersecurity if it is not connected to the underlying services furnished by either party (*e.g.,* ensuring the secure transfer of information between the parties).

We explained in the OIG Proposed Rule that the core function of the donated technology or service must be to protect information by preventing, detecting, and responding to cyberattacks. We also provided a nonexhaustive list of examples of technology and services that we believed would be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity.[92]

We are not finalizing a risk assessment condition (described in more detail in section III.B.8.g), but parties remain free and are encouraged as a general matter to obtain a risk assessment to evaluate their cybersecurity needs. We are finalizing a condition whereby donors may not directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for donated technology or services, or the amount or nature of the technology or services to be donated. This should address the concern regarding parties that improperly use the safe harbor for donations to entice new business.

Comment: Another commenter suggested that in cases where cybersecurity is built into software that gives physicians access to a hospital's computer system, the technology and services should be deemed to be necessary and used predominantly to implement and maintain cybersecurity.

Response: Software that gives physicians access to a hospital's computer system may be protected if it meets all conditions of the safe harbor. However, software that has multiple functions, one of which is cybersecurity, would not meet the necessary and predominant use standard in the introductory paragraph at 1001.952(jj). Conversely, if software has multiple functions but cybersecurity is the predominant function, then that software may be eligible for protection under this safe harbor. Available safe harbor protection of specific software would require an analysis of the facts and circumstances specific to particular arrangement. The advisory opinion process remains available for parties that seek an individualized determination from our office.

Comment: A commenter representing the dental industry urged OIG to permit, with appropriate safeguards, both nonmonetary donations and monetary remuneration for the purchase of cybersecurity technologies and services. The commenter suggested that permitting monetary remuneration in appropriate circumstances could help alleviate the final rule's unintended adverse effects on competition, such as when a donor wishes to supply cybersecurity technology to two competing small providers, and one of the small providers has already purchased the technology but the other has not. The commenter asserted that protecting monetary reimbursement to the first provider and an in-kind donation to the second provider would be fairer than protecting a donation to one competitor and not the other.

Response: We respectfully disagree with the suggestion to protect monetary remuneration or reimbursement for cybersecurity technology and services. As explained elsewhere in this final rule, we view cash and cash-equivalent remuneration to potential referral sources as inherently higher risk under the Federal anti-kickback statute and the Beneficiary Inducements CMP. We also highlight that the example provided by the commenter likely would not satisfy the other conditions of this safe harbor even if it protected monetary remuneration in the form of reimbursement. For instance, reimbursing a provider for technology and services already obtained by a provider would not satisfy the condition that the donation be necessary and predominantly used to implement, maintain, or reestablish effective cybersecurity. In particular, if the recipient already has an effective cybersecurity program, any monetary reimbursement likely would be viewed as duplicative and not used to implement, maintain, or reestablish effective cybersecurity, in addition to being outside the scope of remuneration protected by this safe harbor, which is limited to in-kind remuneration.

Comment: A commenter suggested that the scope of permissible cybersecurity services under paragraph 1001.952(jj)(1) should be broad and varied, provided that the donated services substantially further the interests of strengthening cybersecurity for the end user. The commenter agreed with our proposal that donors should have the discretion to choose the level of cybersecurity technology and services they donate to physicians (or other health care providers) based on a risk assessment of the potential recipient or based on the risks associated with the type of interface between the parties.

Response: We are not adopting the commenter's suggestion. Requiring the donation to be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity is an appropriate safeguard that limits safe harbor protection to the legitimate cybersecurity needs of donors and recipients.

[92] These examples included any services associated with developing, installing, and updating cybersecurity software; any kind of cybersecurity training services, such as training recipients how to use cybersecurity technology, how to prevent, detect, and respond to cyber threats, and how to troubleshoot problems with the cybersecurity technology (*e.g.,* ''help desk'' services specific to cybersecurity); and any kind of cybersecurity services for business continuity and data recovery services to ensure the recipient's operations can continue during and after a cyberattack. 84 FR 55735–55736 (Oct. 17, 2019). Additional examples are in this final rule.

a. Protected Donors

Summary of OIG Proposed Rule: We did not propose in regulatory text to restrict the types of individuals and entities that may qualify for protection under this safe harbor as donors, but we indicated that we were considering some restrictions. We solicited comments on whether particular types of individuals and entities should be ineligible for protection under the safe harbor.

Summary of Final Rule: We are finalizing a policy to protect all donors, without any limitations on the type of individual or entity donating cybersecurity technology and services, as long as the other conditions of the safe harbor are satisfied.

Comment: A number of commenters recommended that the safe harbor protect a broad range of donors, with commenters suggesting that limitations on donors could stifle advances in care coordination, health information security, or both. Commenters stated that other conditions of the safe harbor, including the written agreement requirement and restrictions on taking into account referrals, would effectively safeguard against potential abuses. Commenters provided a number of examples of entities encompassing a range of stakeholder types that desire to make cybersecurity donations. A commenter highlighted potential industry confusion regarding whether the proposed safe harbor would protect donations by cybersecurity vendor firms to patients and requested clarification that such donations do not implicate the Federal anti-kickback statute.

Response: We agree with the commenters who urged protection for a broad range of donor entities and individuals, and we are finalizing an agnostic approach to the types of individuals and entities that may donate technology and services protected by this safe harbor. The need to improve the cybersecurity posture of the health care industry is paramount to restrictions on donors traditionally found in other safe harbors, such as paragraph 1001.952(y). Donations of cybersecurity technology and services are self-protective measures the industry can take because a cybersecurity breach to a recipient's system can have a devastating impact on the donor and others connected to its system.

As we stated in the OIG Proposed Rule, the donor-type restrictions included in the EHR safe harbor at paragraph 1001.952(y) are necessary in that safe harbor and distinguishable from the cybersecurity safe harbor because donations under the EHR safe harbor facilitate the exchange of clinical information between a recipient referral source and the donor, and present a greater risk that the donation is for the donor to secure additional referrals from the recipient or otherwise influence referrals or other business generated. We are confident that the other safeguards in this safe harbor appropriately address the risks associated with permitting parties to donate valuable technology and services to potential referral sources such that a limitation on the scope of protected donors is not necessary.

In response to the comment inquiring about donations from cybersecurity vendor firms, such donations may not implicate the Federal anti-kickback statute or the Beneficiary Inducements CMP (*e.g.,* when the donor is not in a position to induce, influence, or even receive referrals of Federal health care program business or to influence a beneficiary's selection of a particular practitioner, provider, or supplier). Any analysis of donations by cybersecurity vendor firms would require an evaluation of the facts and circumstances to determine whether the Federal anti-kickback statute or the Beneficiary Inducements CMP is implicated.

Comment: Several organizations representing individuals and entities in the laboratory industry recommended making laboratories ineligible as protected donors. For example, a commenter stated that the same concerns surrounding inclusion of pathology practices and laboratories under the EHR safe harbor apply to cybersecurity donations. According to a commenter, when laboratories were protected donors under the EHR safe harbor, physicians implicitly or explicitly conditioned referrals on EHR donations, and EHR vendors encouraged physicians to request more costly EHR software and services from laboratories, putting laboratories in an untenable position. The commenter expressed concern that the same could happen with cybersecurity donations if laboratories were protected under this safe harbor. Another commenter added that protecting laboratories and pathology practices under the safe harbor could negatively affect access to health care services, quality, competition, costs to Federal health care programs, and utilization, and that the proposed condition related to the volume and value of referrals would not sufficiently curb the risk of abuse.

Response: We appreciate the concerns raised by commenters representing the laboratory industry, particularly in light of the industry's experience with the EHR safe harbor. As finalized, the cybersecurity safe harbor does not contain any limitations on the type of individual or entity eligible for protection. All individuals and entities, including laboratories, play a role in protecting the health care ecosystem from cybersecurity threats. The promulgation of this regulation, however, does not require laboratories to donate cybersecurity technology or services, nor does it restrict laboratories from charging fair market value for any cybersecurity technology and services furnished.

To address the concerns about potential recipients conditioning referrals on donations, we are finalizing a condition at paragraph 1001.952(jj)(1)(ii) that prohibits recipients from conditioning referrals and future business on a cybersecurity donation. Donations or solicitations of cybersecurity technology and services conditioned on business or in exchange for Federal health care program referrals would not be protected by this new safe harbor and would be highly suspect under the Federal anti-kickback statute.

b. Permitted Recipients

Summary of OIG Proposed Rule: The proposed safe harbor would protect donations of cybersecurity technology and related services to any individual or entity without limitation, including when the recipient is a patient. We indicated that we were considering whether additional or different safeguards would be appropriate, particularly when the recipient is a patient, and solicited comments on this topic.

Summary of Final Rule: We are finalizing, without modification, our proposal to protect donations of cybersecurity technology and related services to any individual or entity without limitation and without any additional or different safeguards for any recipient.

Comment: A number of commenters agreed with the proposal to protect all potential recipients of cybersecurity donations, including patients. A commenter stated that it is valuable to provide patients with a limited amount of cybersecurity protection to protect patient medical records, particularly as patients and providers become more interconnected. Another commenter recommended protecting donations to patients to facilitate secure transmission of data from devices prescribed to patients and secure communication between the patient and the health care provider. A commenter noted that with the expected increase of patient-generated health data there will be an increased need to ensure that all data

sources and endpoints, including remote monitoring systems used by patients, use good cybersecurity practices.

Response: We agree with commenters that the scope of protected recipients should be unrestricted and should include patients; in particular, cybersecurity donations to patients can serve as a valuable tool in protecting health information, devices, and communications in an increasingly interconnected environment.

Comment: Commenters suggested additional safeguards to ensure prevention of fraud and abuse with respect to donations to patients including: (i) A monetary limit on the donation; (ii) measures that would limit the donation to something the patient does not already possess; and (iii) restrictions against any type of multifunctional software or device. Another commenter perceived, with the growth of application programming interface (API) connections, a need to use techniques such as those outlined by the Open Web Application Security Project (OWASP) to protect the confidentiality and integrity of the patient's health record. Conversely, another commenter suggested that it is unlikely that a patient would be incentivized to seek treatment from a provider solely because of the offer of cybersecurity protection due to the limited nature of these cybersecurity donations.

Response: We believe that the final rule has appropriate safeguards against fraud and abuse with respect to donations to patients without the addition of conditions specific to such donations. For example, we are finalizing the restrictions against donors and recipients conditioning referrals and other business on cybersecurity donations. We also are finalizing the requirement in the introduction paragraph to 1001.952(jj) that a donation be necessary and used predominantly for cybersecurity purposes, as explained in more detail section III.B.8.b.

If a patient already possesses appropriate technology and services, a donation of duplicative or equivalent technology and services likely is unnecessary for cybersecurity purposes, and multifunctional donations are unlikely to satisfy the predominant use standard. There may be specific facts and circumstances in which the safe harbor would protect replacement cybersecurity technology. For example, if a potential recipient's technology is outdated and poses a security risk, replacement cybersecurity technology would likely be necessary depending on the specific facts and circumstances.

We have designed this safe harbor while recognizing the critical need to protect patient data and privacy from cyberattacks. The safe harbor conditions, as finalized, help ensure that cybersecurity donations to patients address that critical need and mitigate the risk of fraud or abuse stemming from such donations. Additional safeguards specific to donations to patients are not needed. This safe harbor also does not change other laws, regulations, or other requirements related to the privacy and security of patient data. Parties seeking to donate cybersecurity technology to a patient may have other obligations under other laws to safeguard patient data.

The safe harbor does not require donations to meet specific standards to protect patient data from cyberattacks or other cybersecurity threats. Parties are free to choose the cybersecurity technology or services that best meet their needs and achieve cybersecurity goals as long as the donation meets all conditions of the safe harbor. For example, while not required for safe harbor protection, parties could elect to agree that any donated technology must satisfy certain third-party standards, is certified by a third party, or is certified or approved through another method to ensure the donation can provide necessary cybersecurity safeguards. Voluntarily meeting a third-party standard does not mean the donation is protected by this safe harbor. To receive safe harbor protection, donated technology or services must otherwise satisfy the conditions of the safe harbor.

Comment: A commenter recommended that OIG consider limiting recipients to those entities with an ''established relationship'' with the donor, such that there is evidence that the donor and recipient interface. The commenter offered as an example a requirement that a physician practice has to have providers who are members of a health system's medical staff in order for such practice to receive a protected donation from the health system. For a protected donation by a physician practice to a patient, the commenter suggested requiring the patient be an ''established patient'' of the practice.

Response: For this cybersecurity safe harbor, we are not adopting the commenter's recommendation to require an established relationship between the donor and the recipient. Although we have incorporated a similar ''established patient'' concept in the local transportation safe harbor at paragraph 1001.952(bb), we believe such limitation might work against the stated goal of this safe harbor to enable widespread improvements to the cybersecurity of the connected health care ecosystem through appropriate donations. We note that other safeguards included in the final safe harbor, such as the requirement in the introduction paragraph to 1001.952(jj) that the donation be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity, as well as restrictions against marketing or related to the volume and value of referrals and other business generated, serve to protect against the concerns addressed by the ''established patient'' concept in other safe harbors, such as the local transportation safe harbor, and are more workable for this safe harbor.

Comment: A commenter stated that donations of technology to a patient may need to be treated differently from donations to a practice or provider because any donation to a patient would rely on a single software use license, which is difficult to implement and manage. Furthermore, the commenter stated that a donation to a patient may require additional services to implement such technology on patients' devices, which is not practical to offer on a large scale. According to the commenter, providers donating such technology may not have the resources to provide support services to patients and may wish to donate technical support services via third parties. But the commenter highlighted that using third parties to provide such services may create additional risks for providers and confusion for patients.

Response: We appreciate that cybersecurity technology and services donations to patients involve different considerations, and we anticipate that donors will evaluate those considerations before making donations to patients. Safe harbors are voluntary, and providers are under no obligation to donate cybersecurity technology and services to patients or to structure arrangements to satisfy the conditions of the safe harbor finalized here. As we stated in the OIG Proposed Rule, protected donations may include services associated with installing and updating cybersecurity software as well as cybersecurity training services, such as training recipients on how to use the technology and troubleshoot problems with the cybersecurity technology. The donor could furnish such donated services on its own or contract with a third party to furnish such services.

We reiterate that a donation to patients also must be necessary. The determination of which cybersecurity technology and services are necessary for patients likely will look much different than such determination with

respect to health care entities. Patients' interaction with or access to a health care provider's system or network is often more limited than another health care provider's interaction or access. For example, patients may interact or access a health care provider's system through a patient portal or by authorizing a third party to access their electronic health data through a mobile application. In those instances, cybersecurity likely is built into the patient portal, the authentication mechanism, or the API services used by the mobile application. We expect that providers evaluating potential donations to patients would take into account existing cybersecurity measures and the nature of the patient's interaction with or access to systems when determining whether any donation to the patient is necessary.

e. Definition of ''Cybersecurity''

Summary of OIG Proposed Rule: We proposed to define ''cybersecurity'' as the process of protecting information by preventing, detecting, and responding to cyberattacks. The proposed definition was derived from the National Institute for Standards and Technology (NIST) ''Framework for Improving Critical Infrastructure Cybersecurity'' (NIST CSF).[93] We intended to define cybersecurity broadly to avoid unintentionally limiting donations.

Summary of Final Rule: We are finalizing this definition with certain clarifications at paragraph 1001.952(jj)(5)(i).

Comment: Several commenters agreed with the proposed definition of ''cybersecurity,'' derived from the NIST CSF, and commenters generally agreed that the final rule should include a broad definition to provide sufficient flexibility. A commenter was generally supportive of the definition of ''cybersecurity'' but believed it should include the process of protecting information through ''identifying'' and ''recovering'' from cyberattacks, to account for the entire lifecycle of a cyberattack. The commenter surmised that the addition of ''recovering'' would protect ''backup services'' that support reestablishing cybersecurity and reduce the impact of ransomware extortion. Relatedly, several commenters noted that the OIG Proposed Rule omitted the word ''reestablish'' in the first condition at paragraph 1001.952(jj)(1), making it inconsistent with the parallel exception to the physician self-referral law as proposed by CMS.

Commenters urged OIG to adopt text that includes ''reestablish'' in the first condition at paragraph 1001.952(jj)(1). Specifically, several commenters recommended that paragraph 1001.952(jj)(1) read, ''[t]he technology and services are necessary and used predominantly to implement, maintain, or *reestablish* effective cybersecurity'' (emphasis added). Commenters asserted that the inclusion of ''reestablish'' in the safe harbor would make explicit that the safe harbor protects post-incident activities, such as the donation of a consultant's time to assist with conducting root cause analyses and identifying needed procedural improvements.

Response: We agree that we should rely on the NIST CSF as a basis to define ''cybersecurity'' and believe that this definition, as finalized, provides sufficient flexibility while also providing an appropriately defined scope of what is protected under the safe harbor consistent with the goals of the safe harbor. As explained in the OIG Proposed Rule, the goal of this definition is to broadly define cybersecurity and avoid unintentionally limiting the scope of donations. For this reason, we also removed the phrase ''certain types of'' before ''cybersecurity technology and services'' from the initial paragraph at 1001.952(jj) to avoid ambiguity; cybersecurity technology and services that meet all conditions of the safe harbor are protected.

We are not adding additional terms to the definition because the definition of ''cybersecurity'' is derived from the NIST CSF glossary.[94] We believe the use of the NIST CSF definition, in combination with the conditions of this safe harbor, provides donors and recipients needed flexibility while also mitigating the risks of fraud and abuse. The NIST CSF is widely accepted across public and private sectors, all types of industries, and international organizations. It provides a commonly understood language for donors and recipients seeking to use this safe harbor to improve their cybersecurity posture. While this safe harbor does not condition protection of donations on compliance with the NIST CSF, we encourage potential donors and recipients to ensure a comprehensive, systematic approach to identifying, assessing, and managing cybersecurity risks.

The additional terms suggested by commenters, such as ''identifying'' and ''recovering,'' also appear in the NIST CSF. The NIST CSF organizes basic ''cybersecurity activities'' into five functions: Identify, protect, detect, respond, and recover.[95] The definition of ''cybersecurity'' in this safe harbor likely would apply to donations of cybersecurity technology and services that are used predominantly and are necessary for these five functions and the related subfunctions and cybersecurity outcomes that are part of the NIST CSF. We have not been persuaded to adopt a more specific definition of cybersecurity by incorporating specific terminology from the NIST CSF and we are finalizing the definition as proposed for the policy reasons explained above.

In response to commenters who said that the term ''reestablish'' was not in the first condition at paragraph 1001.952(jj)(1), we are finalizing a clarification to extend protection to donations that are necessary and used predominantly to implement, maintain or reestablish effective cybersecurity. This change is reflected in the final version of the initial paragraph for 1001.952(jj). As we noted in the preamble to the OIG Proposed Rule, protected donations would include business continuity software that mitigates the effects of a cyberattack and data recovery services to ensure that the recipient's operations can continue during and after a cyberattack. Additionally, as we stated in the OIG Proposed Rule, we intend to align closely with the corresponding CMS exception where appropriate.[96]

We note that the safe harbor does not, however, protect payments of any ransom to or on behalf of a recipient in response to a cyberattack, which we would not view as ''reestablishing'' effective cybersecurity (nor would we view it as nonmonetary remuneration, as required for protection under the safe harbor). Although we believe the proposal sufficiently included this concept, for the reasons stated above we have added the word ''reestablish'' in the final version of the introductory paragraph to 1001.952(jj) to provide clarity and to align with CMS's corresponding physician self-referral law exception for cybersecurity donations.

Comment: A commenter applauded the definition of ''cybersecurity'' for being fairly broad and including donations of APIs. The commenter requested, however, that the definition be modified to account for the so-called three pillars of information security: Confidentiality of information, integrity of information, and availability of information.

[93] *See* NIST CSF, Version 1.1 (Apr. 2018), available at *https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf.*

[94] *Id.* at 45.

[95] *Id.* at 6.

[96] 84 FR 55734 (Oct. 17, 2019).

Response: We are not modifying the definition of cybersecurity. As discussed previously, our intention was to broadly define ''cybersecurity'' and use terminology within an industry-recognized standard. We believe the NIST CSF definition of cybersecurity meets those policy goals.

We recognize, however, that the three pillars of confidentiality, integrity, and availability of information are fundamental concepts to cybersecurity. The NIST CSF similarly recognizes these pillars. An outcome category under the ''protect'' function includes that data ''are managed consistent with the organization's risk strategy to protect the confidentiality, integrity, and availability of information.'' [97] Therefore, the definition of ''cybersecurity,'' which includes ''the process of protecting information,'' accounts for these principles while also providing flexibility and certainty to donors as to the scope of protected cybersecurity donations.

Comment: A commenter stated that the proposed definition of cybersecurity seems oversimplified and is not comprehensive. The commenter suggested that the definition of ''cybersecurity'' should be inclusive of any unauthorized use, even without deliberate criminal activity or a specific cyberattack, and recommended broadening the definition accordingly. Another commenter noted that the proposed definition of ''cybersecurity'' includes the term ''cyberattack,'' which the commenter found both vague and representative of only one type of threat to electronic data. The commenter encouraged OIG to adopt the definition found on the Department of Homeland Security (DHS) website, which describes cybersecurity as ''the process of protecting networks, devices, and data from unauthorized access or use and the practice of ensuring confidentiality, integrity, and availability of information.'' The commenter requested that any change to the definition be employed consistently across other relevant safe harbors (*e.g.,* paragraph 1001.952(y)).

Response: We decline to modify the definition. First, the safe harbor definition of ''cybersecurity'' does not limit donations of cybersecurity technology and services to those that prevent only criminal misconduct. The definition of ''cybersecurity'' is agnostic to the intent—criminal or otherwise—of an ''unauthorized user.'' We also believe the definition used in this final rule, derived from the NIST CSF, is broad enough to address the commenter's concerns about ''unauthorized users'' as well as the definition from the DHS website. Specifically, our final regulatory definition of ''cybersecurity'' is broad enough to result in safe harbor protection for technology and services that protect networks, devices, and data from unauthorized access or use, including those that ensure the confidentiality, integrity, and availability of information.

Comment: One commenter stated that the proposed definition of ''cybersecurity'' fails to capture all aspects of security controls relevant to patient information, systems processing, or retention of patient information. The commenter recommended the following definition for cybersecurity: ''[p]revention of damage to, protection of, and restoration of computers, electronic communications systems, electronic communications services, wire communication, and electronic communication, including information contained therein, to ensure its availability, integrity, authentication, confidentiality, and nonrepudiation; or the prevention of damage to, unauthorized use of, exploitation of, and—if needed—restoration of electronic information and communications systems, and the information they contain, in order to strengthen the confidentiality, integrity, and availability of these systems; or the process of protecting information by preventing, detecting, and responding to attacks.''

Response: We are not adopting this suggestion. Notwithstanding, we believe that the principles underlying the commenter's definition, which are derived from NIST and other Federal Government sources, generally are included in the definition of ''cybersecurity.'' Further, we are not modifying the definition of cybersecurity as suggested by the commenter because some of the commenter's proposed additions to regulatory text could be misread to protect multifunctional equipment. For example, ''restoration of computers, electronic communications systems, electronic communications services, wire communication, and electronic communication,'' could be misread by donors to protect donations of multifunctional hardware and other multifunctional donations (*e.g.,* computers or entire communications systems) as part of restoration efforts, which are not protected by this safe harbor. The safe harbor protects donations of cybersecurity technology and services that are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity.

Comment: Several commenters suggested that OIG finalize a broad and industry-neutral definition of ''cybersecurity'' to permit flexibility for future changes, adaptions, and variations in the dynamic world of cybersecurity. A commenter stated that the proposed safe harbor is shortsighted and should include a more comprehensive definition of potential technology solutions for cybersecurity attacks.

Response: We agree with commenters that the cybersecurity safe harbor should be broad and rely on an industry-neutral definition. Consequently, we are finalizing a definition derived from the NIST CSF. The NIST CSF is industry agnostic and applies to any critical infrastructure in the United States, which includes health care. We are not using a definition that would incorporate specific technology solutions for cyberattacks. Such an approach could make the safe harbor definition obsolete as new cybersecurity technologies are developed and implemented. We believe the broad, neutral definition finalized here allows donors and recipients the flexibility to determine which cybersecurity technology and services are necessary and predominantly used to implement, maintain, or reestablish effective cybersecurity. Additionally, we note that effective cybersecurity is broader than technology solutions. Protected donations of cybersecurity technology and services are just one component of cybersecurity. Regardless of the conditions of this safe harbor, we encourage parties to consult cybersecurity industry standards such as the NIST CSF to ensure a comprehensive, systematic approach to identifying, assessing, and managing cybersecurity risks.

f. Definitions of ''Technology'' and Protection of Hardware

Summary of OIG Proposed Rule: We proposed at proposed paragraph 1001.952(jj)(6) to define ''technology'' as any software or other type of information technology, other than hardware. In the preamble to the OIG Proposed Rule, we noted our concern about donations of valuable, multifunctional hardware being disguised as payments for referrals, but also recognized that some hardware may in fact be limited to cybersecurity functionality, such as two-factor authentication dongles, and indicated that we were considering including such hardware in the safe harbor.

[97] *See* NIST CSF, Version 1.1, pg. 32 (Apr. 16, 2018) available at *https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf.*

Summary of Final Rule: We are finalizing, with modification, our proposed definition at paragraph 1001.952(jj)(5)(ii). Based on public comments, the modified final rule provides that donations of certain hardware will be permitted under the exception as long as the donation satisfies the other conditions of the safe harbor. In particular, we highlight that the introductory paragraph for 1001.952(jj) requires that donations be necessary and used predominantly for effective cybersecurity. In most cases, multifunctional hardware would not be used predominantly for effective cybersecurity and thus would fall outside the scope of protection of this safe harbor.

Comment: Some commenters agreed with using the NIST CSF as a basis for the definition of ''technology'' and recommended that any final regulation allow sufficient latitude for various types of technology classifications (software and certain hardware components) and not be limited to a one-size-fits-all paradigm. Some commenters agreed with excluding hardware from the definition of ''technology'' and, therefore, from protection under this safe harbor, citing program integrity risks. A large number of commenters objected to the exclusion of hardware from the definition of ''technology.'' Many commenters highlighted that the line between hardware, software, services, and other technology that is neither hardware, software, nor a service, is increasingly blurred and such technologies are often packaged together as a bundle. Others suggested that hardware donations are a foundational requirement to operationalize cybersecurity best practices. Some commenters noted that certain cybersecurity software requires specific hardware and sought protection for such hardware. For example, a commenter noted that firewalls involve the use of both hardware and software and suggested that many clinicians would not have the technical knowledge to configure the firewalls. A commenter recommended permitting donation of low-cost hardware and possibly adding a dollar threshold that could not be exceeded for the total donation.

Other commenters highlighted that failing to extend safe harbor protection to multifunctional cybersecurity hardware (or software) would limit the utility of the safe harbor because cybersecurity technology often is not standalone in nature. Commenters provided examples of multifunctional hardware they deemed beneficial to cybersecurity hygiene, such as encrypted servers, encrypted drives, upgraded wiring, physical security systems, fire retardant or warning technology, and high-security doors.

Response: Consistent with our solicitation of comments in the OIG Proposed Rule and in careful consideration of the responses from commenters, this final rule expands the definition to include certain hardware. To receive safe harbor protection, donations of such hardware must satisfy all of the conditions of the safe harbor, and specifically the requirement that the hardware be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity. We intend this condition to make donations of multifunctional hardware ineligible for safe harbor protection in most cases, even if such hardware is low-cost, because such donations likely would not satisfy the predominant use condition. For instance, some of the examples provided by commenters would not satisfy the predominant use standard because by design they have functions that extend well beyond cybersecurity, including servers, drives, upgraded wiring, physical security systems, fire retardant or warning technology, and high-security doors. For example, although the donation of an encrypted server might improve the recipient's cybersecurity, the server likely would not be used predominantly for effective cybersecurity because the recipient is likely to use it predominately for other purposes, such as hosting its computing infrastructure. We note, however, that the safe harbor protects services, including installing cybersecurity software. Therefore, if an entity donates cybersecurity software, it can also install and configure such software on a recipient's system. We do not believe a monetary cap is necessary for this safe harbor.

Comment: A number of commenters urged OIG to expand protection for single-function hardware technologies that have limited or no functionality outside of cybersecurity, such as computer privacy screens, two-factor authentication dongles and security tokens, facial-recognition cameras for secure access, biometric authentication, secure identification card and device readers, intrusion detection systems, data backup systems, and data recovery systems. Some commenters opposed any such expansion.

Response: We agree with commenters that certain hardware is limited to cybersecurity uses and, as stated above, have finalized the definition of ''technology'' so that safe harbor protection includes such hardware. However, in order to receive safe harbor protection, donations of hardware must satisfy all of the conditions of the safe harbor and, specifically, the predominant use requirement in the initial paragraph to 1001.952(jj). Some of the examples provided by these commenters including computer privacy screens, two-factor authentication dongles, security tokens, facial-recognition cameras for secure access, biometric authentication, secure identification card and device readers, intrusion detection systems, data backup, and data recovery systems could be protected by the safe harbor if all conditions of the safe harbor are satisfied because their functionality could be predominantly for effective cybersecurity.

We are not finalizing the additional proposed condition that would have required donors and recipients to conduct a risk assessment prior to donating hardware as a means of attaining safe harbor protection for hardware. As finalized, the safe harbor protects hardware donations the same way that software and service donations are protected, that is by meeting all conditions of the safe harbor.

Comment: A commenter explained that it is important for OIG to recognize and make clear that typically it is not the actual software that is purchased by providers because the software is owned by the vendor. Instead, providers purchase the rights to use the software, which is accomplished through licensing. Therefore, with regards to donations, the software itself will not be donated; it will be the license to use that software. The commenter also recommended allowing installment and repairs to be among the types of technology and services, the donation of which is protected by the safe harbor.

Response: We also recognize that in some instances, providers purchase the rights to use the software, which is accomplished through licensing, and donate that use or license rather than the software itself. Donating such licenses can be protected under this safe harbor in the same way that donating software is protected, if all conditions of the safe harbor are met. We also agree with the commenter that installment and repairs can be included among the protected technology and services, provided that the donations of such installment and repairs squarely satisfy the safe harbor's conditions, including that the donation is necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity.

g. Alternate Proposal

Summary of OIG Proposed Rule: We included an alternate proposal to allow parties to donate hardware, subject to

the other conditions of the proposed safe harbor, if such hardware is reasonably necessary based on a risk assessment of the donor and recipient.

Summary of Final Rule: We are not finalizing this alternate proposal.

Comment: Several commenters supported including hardware and did not agree that a risk assessment should be required for protected donations of hardware. A commenter observed that while donors should be free to require and even donate a cybersecurity risk assessment, adopting such a requirement to protect donations of hardware could slow the proliferation of cybersecurity technology. A commenter objected to requiring a written risk assessment from either party, or in multiparty arrangements from any party. Another commenter stated that OIG should not adopt a security framework tying cybersecurity technology to particular industry standards and should not require the preparation of special security risk assessments or management documents. Instead, the commenter recommended that OIG recognize any safeguard that advances the HIPAA security standards.

Response: For the reasons stated above, we are not finalizing this alternative proposal. Parties may have other legal obligations to conduct risk assessments, and this safe harbor does not affect any such requirements. Furthermore, we are not requiring cybersecurity technology and service donations to meet specific standards. Parties also remain free to donate cybersecurity risk assessments under this safe harbor if all of the other conditions are satisfied. Parties are encouraged to perform risk assessments to determine donor and recipient vulnerability to cyberattacks and to assist in creating their own cybersecurity programs.

Comment: Several commenters recommended requiring a risk assessment to receive protected hardware or other donated cybersecurity products for various reasons. For example, a commenter highlighted that a risk assessment can determine what type of protection is needed when there are vulnerabilities and ensure that the cybersecurity product is effective once implemented. A commenter requested that it not be a requirement for the recipient to perform any risk assessment, as they may not have the appropriate knowledge and expertise to do so. Instead, the commenter suggested that the recipient have the option to perform the risk assessment if they have the knowledge and expertise to do so; otherwise, it could be completed by the donor or a qualified third party.

Several commenters suggested that any definition or scope of ''risk assessments'' should rely on definitions set out by NIST publications and further suggested that OIG should rely on the comprehensive NIST definition. Some commenters requested that OIG provide template risk assessment documentation.

A commenter suggested that parties be required to maintain the initial risk assessment, which could be used to compare the ''baseline'' risk assessment to a future risk assessment to help understand whether any previously identified gaps were resolved.

Response: For reasons previously stated, we are not requiring a risk assessment as a condition of this safe harbor. We agree that cybersecurity risk assessments are valuable tools that can evaluate vulnerabilities and identify cybersecurity solutions, and parties remain free to obtain such risk assessments, or to donate them as long as the conditions of this safe harbor are met. For example, one method parties might use to establish that a donation was necessary for cybersecurity is to utilize findings from a legitimate risk assessment to demonstrate that a recipient had a vulnerability that was necessary to mitigate.

h. Scope of Protected Technology and Services

Summary of OIG Proposed Rule: We proposed to protect a broad range of technology and services, excluding hardware, and solicited comments on this approach.

Summary of Final Rule: We are finalizing protection for a broad range of technology and services, including certain hardware. We provide additional clarity on the scope of this protection and several examples below.

Comment: Most commenters recommended that we finalize protection for a broad range of donations, and some requested specific language or clarifications. In particular, several commenters asked OIG to consider the implications of cloud-based and subscription-based products and services. Another commenter requested OIG provide clarity related to the scope of protected donations through examples of the types of software and services allowed (*e.g.,* provision of a full-time cybersecurity officer). Some commenters also noted that a cybersecurity-specific help desk may not be realistic and recommended that OIG protect donations of general help desk services, whether through the donor's IT department or the vendor's help desk services. A commenter urged OIG to protect patches and software updates.

Response: As finalized, the safe harbor protects donations of a broad range of cybersecurity technology and services. This includes certain cybersecurity hardware, as discussed above, as well as a multitude of cybersecurity services and technology. Cybersecurity services and technology would include both locally installed cybersecurity software and cloud-based cybersecurity software, including patches and updates of such software or patches and updates of other software or programs if the patch or update is predominantly for cybersecurity purposes. Protected donations, however, are constrained by the initial paragraph to 1001.952(jj), which requires that the donation is necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity. This safe harbor is intended to cover a wide range of cybersecurity technology and services that have specific functionality, as constrained by the initial paragraph for 1001.952(jj). This approach means that most technology and services that include cybersecurity as one function of multiple functions will not be protected by this safe harbor. For instance, depending on the facts and circumstances of a particular arrangement, donating a virtual desktop that includes access to programs and services beyond cybersecurity software likely would not be protected because the donation likely would include functions not necessary and predominantly used to implement, maintain, or reestablish effective cybersecurity, such as claims and billing applications. We explicitly decided not to protect technology or services that may provide some beneficial cybersecurity effects as one feature of a broader suite of services because that broad scope of protection could apply to nearly any technology or service. We believe such a broad scope of protection under this safe harbor would elevate the risk that valuable donations could improperly influence the recipient. Understanding those tradeoffs, we conclude that the significant need for the health care system to improve cybersecurity is better served by this safe harbor only protecting cybersecurity technology and services that have specific functionality, as constrained by the initial paragraph to 1001.952(jj), but with fewer other conditions that would limit certain aspects of a donation (*e.g.,* a monetary cap on the value of a donation).

Donors and recipients that would like to protect the donation of technology or services that are not necessary or are

used predominantly to implement, maintain, or reestablish cybersecurity should assess those potential arrangements under the Federal anti-kickback statute as well as other potentially applicable safe harbors, such as the EHR safe harbor at paragraph 1001.952(y). Alternatively, the advisory opinion process remains available to parties seeking a legal opinion regarding the scope of the safe harbor as applied to a specific set of facts and circumstances.

For the same reasons, we are not extending protection for donations of general IT help desk services because cybersecurity is not the predominant use of such services. However, we are aware of cybersecurity-specific software and services that include customer service and help desk features for cybersecurity assistance. Such help desk services, if they are necessary and predominantly used for implementing, maintaining, or reestablishing cybersecurity, could meet the introductory paragraph for 1001.952(jj) and may be protected by this safe harbor if all other conditions are met. Relatedly, donating services through a donor organization's primary service desk or IT help desk, limited to reporting cybersecurity incidents, could satisfy this requirement because the service or help desk responsibilities would be used predominately for cybersecurity incident reporting. Staffing a recipient's practice with a full-time cybersecurity officer, however, would only be protected by this safe harbor if that officer's duties were used predominately for implementing, maintaining, or reestablishing effective cybersecurity and were necessary. If the officer performed general information technology services or provided other non-cybersecurity value to the recipient's business, then the donation may not meet the requirements in the initial paragraph for 1001.952(jj).

Comment: A commenter asked OIG to clarify that services such as assurance, assessment, and certification programs that incorporate cyber-risk management could receive safe harbor protection.

Response: To the extent the assurance, assessment, and certification programs that incorporate cybersecurity risk management suggested by the commenter satisfy all of the conditions of the safe harbor, including the requirements in the initial paragraph for 1001.952(jj), they could be protected. We note, however, that if cybersecurity is just one component or feature of the assurance, assessment, and certification programs referenced by the commenter, then the other features are not likely to be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity, and the cybersecurity safe harbor would not protect the referenced services, although they could be protected under another safe harbor.

Comment: A commenter expressed concern that the OIG Proposed Rule would create separate safe harbors for various types of technology, resulting in a piecemeal approach to tools that must work together to drive care coordination. The commenter urged OIG to broaden the cybersecurity items and services safe harbor and the EHR safe harbor to be flexible enough to protect technology that can help facilitate the movement to value-based care. Several commenters specifically recommended that any final cybersecurity safe harbor protect data analytics and reporting functionalities. Another commenter asked that OIG clarify that arrangements involving sharing data and technology, including cybertechnologies that keep the data secure, are not illegal remuneration when used for care coordination purposes.

Response: We recognize that multiple safe harbors may protect various types of technology donations. Several safe harbors finalized elsewhere in this final rule protect certain remuneration to facilitate care coordination and the transition to value-based care, such as the value-based safe harbors at 1001.952(ee)–(gg). Data analytics, reporting functionalities, and other information technology used to facilitate the movement to value-based care may be protected under these safe harbors, provided the arrangement squarely satisfies the conditions of any applicable safe harbor. However, we note that cybersecurity items in and of themselves likely would not meet the definition of the ''coordination and management of care,'' as explained in the preamble above. Relatedly, data analytics and other information technology, when coupled with a cybersecurity donation, would not meet the requirement that the donation be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity.

We emphasize that arrangements involving sharing data could potentially involve remuneration that implicates the Federal anti-kickback statute. For instance, while standing on its own, basic sharing of patient records for purposes of care coordination or treatment of patients is unlikely to implicate the statute, the provision of data analysis, data aggregation, or other services of independent value to the recipient likely would be the sort of remuneration that implicates the statute. Any assessment of Federal anti-kickback statute implications, available safe harbor protection, and potential liability under the statute, would require an analysis of the facts and circumstances specific to the particular arrangement.

Data analytics and other information technology that may be protected by the value-based safe harbors at 1001.952(ee)–(gg) can include built-in cybersecurity protections. For example, those safe harbors do not require the data analytics software to be free from cybersecurity protections to meet their conditions. Such software might normally include security features, such as a secure login and authentication, as part of the normal software development and could be protected by the value-based safe harbors, depending on the facts and circumstances.

Where parties seek safe harbor protection for the donation of technology, parties do not need to protect separate functions of that technology under different safe harbors if the donation meets the terms of a single safe harbor. This cybersecurity safe harbor is intended only to protect cybersecurity technology and services. Other safe harbors protect donations that may include cybersecurity features as part of a broader donation, without regard to whether the cybersecurity features would meet the requirements of the cybersecurity safe harbor (*e.g.,* a donation of data analytics software that includes cybersecurity features may be protected by the value-based safe harbors at 1001.952(ee)–(gg), or an EHR system with cybersecurity features may be protected by the EHR safe harbor at 1001.952(y)).

Unless the data analytics and reporting functionality is predominantly used to analyze and report on cybersecurity threats or attacks (rather than more broadly facilitating the movement to value-based care), then it typically would not satisfy the initial paragraph for 1001.952(jj), which requires that the cybersecurity donation be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity.

Comment: A commenter recommended that OIG clarify the scope of what the cybersecurity technology and services must protect, such as cybersecurity to protect electronic health records, medical devices, or other information technology that uses, captures, or maintains individually identifiable health information. The commenter stated that the proposed safe harbor was silent as to the ''object'' of the cybersecurity protection and an explicit statement setting broad parameters about the purpose of

donated cybersecurity technology and services would provide guidance and cover future technology advances. Another commenter encouraged OIG to permit donations related to medical device cybersecurity, which the commenter identified as a growing area of vulnerability. The commenter posited that promoting the security of medical devices would create added protection for patient privacy and safety.

Response: We are not defining the ''object'' or ''subject'' of the cybersecurity protection. The safe harbor protects a wide range of cybersecurity technology and services that are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity. If all other conditions of the safe harbor are satisfied, this could include cybersecurity donations in connection with medical devices, EHR, and other information technology.

Comment: A commenter supported the inclusion of a broad array of cybersecurity services as part of the safe harbor, including numerous examples from the OIG Proposed Rule. In addition, the commenter recommended adding services to the list included in the OIG Proposed Rule, such as consulting services deployed not to conduct only a risk assessment or analysis, but to work with the practice to develop and implement specific cybersecurity policies and procedures. The commenter also suggested protection for subscription fees to vendor security products that assist practices in developing policies and procedures in support of a risk assessment. Another commenter requested that OIG provide further examples of what would and would not be protected by the safe harbor.

Response: We provided examples of items and services that would be protected by this safe harbor in the preamble to the OIG Proposed Rule that are still valid under the final rule and provide additional examples in this final rule.[98] The examples included in the OIG Proposed Rule apply to the safe harbor, as finalized, and continue to illustrate the scope of the technology and services potentially protected by the safe harbor. We emphasize that we intend for the safe harbor to protect a broad array of technology and services. Donations of services that meet all conditions of this safe harbor would be protected. That would include donations where the donor arranges for or otherwise pays for third-party vendors or consultants to provide cybersecurity services that are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity. We note, however, that reimbursing a recipient or providing monetary remuneration for such services would not be protected by this safe harbor because the safe harbor only protects nonmonetary remuneration.

The advisory opinion process remains available for parties seeking a legal opinion regarding the scope of the safe harbor as applied to a specific set of facts and circumstances.

Comment: A commenter asked OIG to include protection for implementation, management, and remediation services within the scope of this safe harbor, as these will fully optimize donations.

Response: The safe harbor would protect donations that include implementation, management, and remediation services, including those provided through a third party, if all conditions of the safe harbor are satisfied. As we stated in the OIG Proposed Rule, the safe harbor may protect services such as developing, installing, and updating cybersecurity software, and training recipients how to use it. We also stated in the OIG Proposed Rule that ''cybersecurity as a service'' may be protected, which includes third-party services for managing and monitoring the cybersecurity of a recipient.

Comment: While many commenters expressed concern about the effectiveness of the safe harbor if it does not protect a broad scope of technology and services, other commenters recommended limiting the scope of protected technology and services. A commenter noted that effective cybersecurity protection could require a whole suite of services, such as active management, monitoring, and developing an effective response system if an issue arises, and it may not be possible for an outside entity to provide such a broad range of services.

Response: This safe harbor protects a wide range of cybersecurity technology and services that satisfy the conditions of the safe harbor. It is intended to remove one actual or perceived barrier to improving the cybersecurity posture of the health care industry. While this safe harbor does not and cannot solve all cybersecurity issues for the health care industry, OIG believes that cybersecurity donations are just one tool that the health care system can use to improve its cybersecurity. We encourage providers and other actors to engage in other cybersecurity efforts, consistent with industry standards and applicable laws, to improve the cybersecurity of the entire health care system.

i. Monetary Cap

Summary of OIG Proposed Rule: We solicited comments on whether the safe harbor should include a monetary value limit on the total amount of donations that a donor can make to a recipient.

Summary of Final Rule: We are not finalizing a condition imposing any monetary limit.

Comment: A commenter recommended that if the final safe harbor protects hardware, OIG should not impose any cap on the value of the donated hardware. Another commenter encouraged OIG to finalize the safe harbor without imposing a monetary limit on the value of applicable remuneration. Some commenters recommended a cap as a potential safeguard.

Response: We are not finalizing any monetary cap on the value of remuneration protected by this safe harbor. We believe most cybersecurity donations are made for purposes of self-preservation from the risk of cyberattack. Therefore, donors are incentivized to donate what is required to achieve effective cybersecurity and not make excessive donations beyond the scope of what is needed to protect themselves. Furthermore, the initial paragraph for 1001.952(jj) limits donations of technology and services to those necessary and used predominantly to implement, maintain, or reestablish cybersecurity, which also serves to limit any excessive value of donations. The conditions at paragraphs 1001.952(jj)(1) and (2) ensure that the cybersecurity safe harbor does not protect donations that are tied to Federal health care program referrals or are otherwise conditioned on Federal health care program business. These conditions help mitigate the risk that more valuable donations may lead to more referrals or future business.

The threat-reduction purpose of cybersecurity technology and the conditions of the safe harbor work together to limit the risk of fraud or abuse caused by improper donations and a monetary cap is not needed for the cybersecurity safe harbor.

j. Deeming Provision

Summary of OIG Proposed Rule: We solicited comments on whether to create a provision in the final rule that would allow donors and recipients to demonstrate compliance with the condition at paragraph 1001.952(jj)(1) by meeting certain additional standards. Specifically, we suggested a ''deeming provision'' that would allow donors or recipients to demonstrate that the donation satisfies proposed paragraph

[98] 84 FR 55735–6 (Oct. 17, 2019).

1001.952(jj)(1) if it furthers a recipient's ability to comply with a written cybersecurity program that reasonably conforms to a widely recognized framework or set of standards, such as one developed or endorsed by the National Institute of Standards and Technology (NIST) or another American National Standards Institute-accredited standards body, such as the International Organization for Standardization.

Summary of the Final Rule: We are not finalizing a ''deeming provision.''

Comment: A number of commenters supported the inclusion of a ''deeming provision'' in the final rule and offered suggestions on how to implement such a provision. Several commenters suggested that the ''deeming provision'' should apply if the donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to a widely recognized cybersecurity framework, such as one developed by NIST, or guidelines developed by the Department of Health and Human Services Office for Civil Rights (OCR) in collaboration with the Office of the National Coordinator for Health Information Technology (ONC). One commenter recommended that any reference to cybersecurity standards, frameworks or risks be based on existing independent frameworks, ideally drawn from NIST standards.

Response: We are not finalizing a ''deeming provision'' for the cybersecurity safe harbor. We are concerned that a deeming provision could have the inadvertent effect of protecting multifunctional hardware, software, or other technology and services because the donation conforms to a written cybersecurity protocol following industry standards. Specifically, if a donor or recipient were to demonstrate that a donation of hardware furthered its compliance with a written cybersecurity program that includes items such as laptops, servers, or other types of multifunctional hardware, parties may use the ''deeming provision'' in attempting to protect hardware that is not necessary or used predominantly to implement, maintain, or reestablish effective cybersecurity. Although we are not finalizing a voluntary ''deeming provision,'' parties are encouraged to consider implementing cybersecurity programs that follow widely recognized industry frameworks. Parties may also voluntarily include their own standards to apply to donations.

However, even if donations further compliance with a written cybersecurity program that is consistent with a widely recognized industry cybersecurity framework or a party's own standards, that does not automatically mean that any cybersecurity donation is ''deemed'' necessary or used predominantly to implement, maintain, or reestablish effective cybersecurity. Parties should undertake a careful analysis of any donations for which they seek safe harbor protection to ensure compliance with all conditions of the safe harbor.

Comment: Some commenters urged that any reference to standards or frameworks used in any ''deeming provision'' be illustrative and not exclusive, so as to avoid unnecessary constraints and allow for the application of future frameworks. Another commenter agreed with inclusion of a ''deeming provision'' but recommended that such provision remain voluntary. Several commenters objected to any ''deeming provision,'' noting that it would add an unnecessary burden without providing any meaningful protection against fraud and abuse. A commenter stated that physicians may struggle to understand what ''reasonable conformance'' looks like or when a framework or standard is considered ''widely recognized.'' A commenter stated that a stringent ''deeming provision'' could create additional barriers to mitigating the risks of cybersecurity threats. One commenter sought clarity on the ''deeming provision,'' asking whether the recipient must show financial need to satisfy the ''deeming provision,'' and another commenter supported a ''deeming provision'' when the cost of the donation of technology and services exceeds a specified monetary limit.

Response: Safe harbors are voluntary; this safe harbor does not require any individual or entity to offer free or discounted cybersecurity technology or services, nor does it require any individual or entity to structure any donations of cybersecurity technology and services to satisfy the conditions of the safe harbor. Notwithstanding, for the reasons stated above we are not finalizing a ''deeming provision'' in this safe harbor. We also agree with the commenter that parties may struggle to understand what ''reasonable conformance'' looks like or when a framework or standard is considered ''widely recognized.'' Without selection of one or more specific frameworks, any ''deeming provision'' could be subject to manipulation.

Comment: One commenter suggested that OIG adopt the same ''deeming provision'' that appears in the EHR safe harbor at paragraph 1001.952(y)(2).

Response: We decline to adopt the commenter's suggestion. The ''deeming provision'' included in the EHR safe harbor at paragraph 1001.952(y)(2) relates to donations of EHR items and services satisfying the interoperability condition in paragraph 1001.952(y)(2) using ONC Certification standards rather than the ''necessary and used predominantly'' standard in this cybersecurity safe harbor. Therefore, the commenter's suggested ''deeming provision'' is not applicable in this context and, for the reasons stated above, we are not finalizing any ''deeming provision'' in this safe harbor.

k. Volume and Value Condition

Summary of OIG Proposed Rule: We proposed at paragraph 1001.952(jj)(2) that donations would not be protected under this safe harbor if donors directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated. Donations also would not be protected if donors condition donations of technology or services, or the amount or nature of the technology or services to be donated, on future referrals. Similarly, we proposed at paragraph 1001.952(jj)(3) that donations would not be protected if the recipient or the recipient's practice (or any affiliated individual or entity) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

Summary of Final Rule: We are finalizing, without modification, these conditions, but renumbering them as 1001.952(jj)(1) and (2).

Comment: Commenters generally supported the provision restricting donors from directly taking into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services donated. Commenters also supported OIG's proposal that potential recipients should not be permitted to condition future business with the donor on the receipt of cybersecurity donations. A commenter recommended that OIG set guardrails to ensure that industry stakeholders do not donate cybersecurity in order to influence referral patterns. Some commenters also agreed that OIG should not finalize a list of selection criteria that, if met, would be deemed not to directly take into account the volume or value of referrals or other business generated between the parties, similar to the provision within the EHR safe harbor at paragraph

1001.952(y)(5). A commenter agreed that donations of cybersecurity technology and services do not present the same risks as donations of EHR software and information technology. Thus, a list is unnecessary.

Response: We are finalizing paragraphs 1001.952(jj)(1) and (2) as proposed. We agree with commenters who recommended that we not include a list of selection criteria deemed not to directly take into account the volume or value of referrals, similar to paragraph 1001.952(y)(5). We agree with the commenter who described such a list as unnecessary. Additionally, the safe harbor conditions we are finalizing, viewed in their totality, guard against donations to influence referral patterns, so additional guardrails are unnecessary.

Comment: A commenter representing hospitals and health systems expressed concern that the provision of cybersecurity technology and related services to physician practices could increase the risk of fraud and abuse if the donations are used as a bargaining chip, thus facilitating cost-shifting from entities in need of such services and potential donors, rather than cooperation between the entities. Another commenter representing the laboratory industry expressed concerns about physicians starting or encouraging ''bidding wars'' between laboratories, insinuating that the laboratory that offers or makes the most generous donation will get the physician's referrals (and, likewise, some laboratories in fact may act inappropriately and promise a donation in exchange for future referrals).

Response: We acknowledge the commenters' concerns about inappropriate donations designed to induce referrals. We are finalizing paragraphs 1001.952(jj)(1) and (2) as proposed to preclude such conduct from protection under this safe harbor. Like the commenters, we are concerned about the ''bargaining chip'' and ''bidding war'' scenarios, and we emphasize that donors that condition donations on referrals—and potential recipients who demand donations as a condition of doing business or continuing to do business—would not qualify for protection under this safe harbor. Furthermore, such offers and solicitations may violate the Federal anti-kickback statute.

Comment: A provider trade association noted that donations of cybersecurity technology and services are typically made by software developers and medical device manufacturers, not providers. The same trade association cautioned that cybersecurity-related donations should be based on risk to the donor's own software, systems, or network, and suggested that such donations should be available to all similar entities with similar risk assessments and without regard to business relationships or affiliations.

Response: As we stated above, this safe harbor is agnostic to the types of individuals and entities donating the protected cybersecurity technology and services. We believe the requirement that donations be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity, combined with requirements related to the volume and value of referrals and other business generated, provide safeguards to ensure that donations are made for necessary cybersecurity purposes.

In response to the commenter's suggestion that donations should be made available to similarly situated entities, we note that the safe harbor is voluntary. A donor can choose the entities to which it donates. Furthermore, it is likely impracticable that donors would make donations available to all similar entities with similar risk assessments. Even in those circumstances, the donor and a potential recipient may have needs that are different than those for other similarly situated entities based on the specific cybersecurity needs inherent in connecting to the specific systems with which the donor interacts. We emphasize that determining whether a cybersecurity donation meets the conditions of the safe harbor requires an analysis of the specific facts and circumstances.

l. Recipient Contribution

Summary of OIG Proposed Rule: We did not propose a requirement that donors of cybersecurity technology and services collect a monetary contribution from recipients. In connection with our alternative proposal that would cover hardware, we solicited comments on whether we should require a contribution from a recipient if a donation included hardware.

Summary of Final Rule: We are not finalizing a contribution requirement as a condition to this safe harbor, regardless of whether hardware is included in the donation.

Comment: Many commenters agreed with our proposal not to require a recipient of protected cybersecurity technology and services to contribute to the overall cost of the donation. Commenters suggested that a contribution requirement in the context of this safe harbor may act as a barrier to donations because it may be: (i) Administratively burdensome to calculate or track contributions; (ii) imprecise; or (iii) cost-prohibitive for recipients who lack adequate resources to contribute. A commenter stated that the pressing requirement to upgrade the cybersecurity of the nation's health care systems should not be held hostage to the ability of capital-constrained medical practices to pay money for such security. Several commenters agreed with our conclusion in the OIG Proposed Rule that forgoing a contribution requirement in this safe harbor would free recipients' resources to invest in other technology not protected by the safe harbor, such as updating legacy technologies. Several commenters requested that donors have the option to require a contribution from recipients.

Response: We agree with commenters who recommended against including a contribution requirement in this safe harbor. Rather than investing resources in a contribution, the final rule frees up recipients to invest resources in other technology not protected by the safe harbor, such as updating legacy multifunctional hardware that may pose a cybersecurity risk or simply investing in their own computers, phones, and other hardware foundational to their businesses, caring for patients, and interacting with their providers. Additionally, we are finalizing only those conditions that are critical to guarding against fraud and abuse in the context of cybersecurity donations in order to provide regulatory flexibility for donations intended to counterbalance the significant cybersecurity threats against the nation's health care ecosystem.

We have concluded that a contribution requirement would be burdensome in the context of cybersecurity donations because the necessity of donated services may vary unpredictably—varying weekly or even daily—in response to cybersecurity threats. We understand that cybersecurity patches and updates are frequent and would need to be applied or aggregated across an entire set of recipients using the same technology or services, further complicating contribution amounts for each end user. Also, we are concerned that recipients might be unwilling or unable to accept cybersecurity donations due to potentially unpredictable costs they might incur after the initial donation. In the context of cybersecurity donations, a contribution requirement would pose a barrier to donations that, on balance, is outweighed by the need for widespread improvement of

cybersecurity hygiene in the health care industry.

As we stated in the OIG Proposed Rule, donors are free to require recipients to contribute to the costs of donated cybersecurity technology and services as long as the determination of a contribution requirement, or the amount of the contribution, does not take into account the volume or value of referrals or other business between the parties. For example, if a donor donates without any required contribution cybersecurity services to a high-referring physician practice but requires a low-referring physician practice to contribute to the cost of such services, the donor could violate the conditions at paragraph 1001.952(jj)(1)(i) and (ii).

Comment: Several commenters supported a contribution requirement for various reasons. One commenter representing the laboratory industry discussed that industry's experience with the EHR safe harbor at paragraph 1001.952(y), concluding that absent a contribution requirement, vendors have little incentive to offer competitive pricing. The commenter stated that its experience with EHR donations may extend to cybersecurity donations, and cybersecurity technology vendors' sales representatives may urge physicians that require cybersecurity software and services to direct their requests to laboratories likely to make a donation, increasing the demand for the vendors' cybersecurity technology. Another commenter suggested that although recipients should have a vested interest in the products they are using, a 15 percent contribution may be too high for some providers, suggesting that a smaller contribution could be a fair compromise. A number of commenters requested a carve-out to any finalized contribution requirement for small and rural providers, those in medically underserved areas, and federally qualified health centers. Several commenters argued for consistency in any contribution requirement across safe harbors, noting that because cybersecurity is part and parcel of other technology it could impose undue complications to require recipients to contribute to some donations but not others. Several commenters asserted that OIG should consider a flexible contribution requirement that would provide for a comparable investment across provider types rather than a flat percentage contribution.

Response: For the reasons stated in the preceding response, we have concluded that a contribution requirement of any percentage is not appropriate for this safe harbor. Donations of cybersecurity technology and services do not present the same type or magnitude of risks as donations of electronic health records software and other information technology. As we stated in the OIG Proposed Rule, cybersecurity donations, if legitimate, are more likely to be based on considerations such as security risks—especially the exposure of the donor when connecting to the recipient—and are less likely to be based on considerations relating to the volume and value of referrals or other business generated. We believe the safeguards in the final safe harbor, including restrictions against recipients conditioning their referrals or business on donations, are sufficient to account for the potential pressure from vendors. Furthermore, suspected fraud and abuse can be reported to OIG's hotline at *https://oig.hhs.gov/fraud/report-fraud/index.asp.*

m. Patching and Updates

Summary of Proposed Rule: Related to the issue of recipient contribution, the OIG Proposed Rule discussed the unique, practical difficulties of a contribution in the context of cybersecurity patching and updates.

Summary of Final Rule: We are not finalizing any specific regulatory text relating to patching and updates. We view these as protected under the safe harbor if all other conditions of the safe harbor are satisfied.

Comment: Several commenters asked that we protect the costs or services associated with ongoing cybersecurity software updates and other patches. A commenter highlighted that patching and updates are critical to managing cybersecurity risks, and that prohibiting their donation could neutralize any benefits resulting from any final safe harbor. A commenter noted that, given the fast-paced nature of developments in cybersecurity, it is likely that new tools will need to be deployed on at least an annual basis. Another commenter requested clarification regarding whether accepting a routine or critical update would result in loss of safe harbor protection, noting that patching is sometimes given to providers for free (because it is built into the contracts with vendors) and some patches may be focused on security while others may be more general.

Response: We agree with commenters that patching and updates are critical to managing cybersecurity risks, and this final safe harbor protects such patches and upgrades if all conditions of the safe harbor are squarely satisfied. We note that this final rule does not require a contribution from the recipient, as discussed above, so routine patches and upgrades given for free to recipients will not result in loss of safe harbor protection, as long as all safe harbor conditions are met. Donors who collect a percentage contribution from any recipient, according to the written agreement with the recipient, may need to collect a contribution for any patches and updates pursuant to the terms of the parties' agreement. It is possible for donors to structure any required recipient contribution in a number of ways as long as neither the decision to collect the contribution nor the amount or nature of the contribution is based on the volume or value of referrals or other business generated between the parties. For example, a donor is free to structure donations that require a percentage or sum certain contribution for the initial cybersecurity donation but not for subsequent patches and upgrades as long as the donor does so consistently and according to the terms of the written agreement.

n. Writing Requirement

Summary of OIG Proposed Rule: We proposed at proposed paragraph 1001.952(jj)(4) that a donor and recipient set forth a written agreement that is signed by the parties and that describes the technology and services being provided, and the amount of the recipient's contribution, if any.

Summary of Final Rule: We are finalizing, with modification, a writing requirement at paragraph 1001.952(jj)(3). We are not requiring that the writing be a single document, and we made certain clarifications, including that the signed documentation must include a general description of the technology and services provided.

Comment: Commenters generally supported a writing requirement. A commenter asserted that a written agreement between donors and recipients of cybersecurity technology and services will bring transparency to the donation process. Another commenter agreed that a signed agreement is necessary to ensure that both parties understand what is being donated and the terms of the agreement, including long-term maintenance and support of the technology.

Response: We agree with commenters that a writing requirement will bring transparency to the donation process and ensure that the parties understand the scope of the donation and the responsibilities of both parties. The safe harbor's writing requirement mandates that parties articulate in writing a general description of the donation, and if the donor will require a contribution

the parties must specify that amount. We anticipate that parties would include in their general description of the donation some details about the initial technology or service provided as well as any provision of long-term maintenance, support, patching, or updates they intend to include within the scope of the donation. We do not anticipate that parties will specify every unforeseen item or service that might be necessitated by a future update.

Comment: A commenter stated that a written agreement between donors and recipients is an acceptable safeguard as long as any requirement for such agreement is reasonable in scope. The commenter stated that required terms and conditions in the agreement should be limited, given the nature of the donation and the relationship between the parties. For example, the commenter stated that the safe harbor's writing requirement should not compel written terms other than to describe: (i) The technology, services, or both to be donated; (ii) commercial terms as necessary to meet the safe harbor; and (iii) warranties by each party to use such technology in compliance with applicable laws and regulations. The commenter also urged OIG to provide a publicly accessible template cybersecurity donation agreement or standard cybersecurity donation terms.

Response: We have designed the final writing requirement to be reasonable in the context of the other conditions in the cybersecurity safe harbor. We decline to add the specific examples of terms and conditions to regulation text or provide any template cybersecurity donation agreement or standard cybersecurity donation terms for parties to use, as suggested by the commenter. This condition requires that parties include a general description of the cybersecurity technology and services to be provided and, if any contribution is required, the parties must specify the amount. The parties are free to add other terms to their documentation related to a cybersecurity donation.

Comment: A commenter appreciated our preamble explanation of the safe harbor's writing requirement but requested that the proposed regulatory text include the word ''general'' or ''generally'' so that donors and recipients do not unnecessarily include every item or potential service in a written agreement. The commenter urged OIG to revise the regulatory text of the writing requirement to read as follows: ''[generally] describes the technology and services being provided. . . .'' The commenter also requested clarification concerning any value-related writing requirements. The commenter stated that the proposed regulatory language includes the amount of the recipient's contribution (if any), while the preamble states that the written agreement requires a reasonable estimate of the value of the donation. The commenter supported only including the recipient's contribution (if any), but requested that if we include a writing requirement related to specifying the value of the donation, then OIG should require the writing to include a reasonable estimate of the value of the donation so as to not introduce any concept of fair market value or the need to hire a valuation consultant to determine a reasonable estimate.

Response: We appreciate the commenter's concern about the language included in the proposed regulation text at proposed 1001.952(jj)(4), and we are finalizing a writing requirement that includes some changes suggested by the commenter. Specifically, the final regulatory text of this safe harbor's writing requirement at paragraph 1001.952(jj)(3) requires that the signed writing include a general description of the technology and services being provided and the amount of the recipient's contribution, if any. Through this final writing requirement, we do not intend to: (i) Introduce any fair market value requirement; (ii) force parties to determine the fair market value of the donation; or (iii) compel the parties to hire a valuation consultant. For purposes of this condition, we interpret ''the amount of the recipient's contribution, if any'' to mean either the sum certain a donor will collect as contribution or, if the donor will collect a percentage of the total value of the donation, the percentage that will be applied. To be clear, this safe harbor does not include a recipient contribution requirement; however, if the donor chooses to require that the recipient contribute, that contribution must be documented in writing. We also note that if the scope of the donation changes materially over time, such as when a donor provides more or fewer technology or services than originally anticipated in the scope of the arrangement, or if the parties alter the contribution requirement (if any), we think that best practices would have the parties document such modifications in writing. If the donor requires a contribution that applies to the initial value of the donation but not the subsequent value of patching and upgrades, we anticipate that the writing would specify such terms.

Comment: A commenter objected to OIG's proposed documentation requirement, stating that it should be scaled back to avoid imposing burdensome writing requirements on the parties. The same commenter argued that a simple acknowledgement that the software donation has been or will be made available should be sufficient.

Response: We do not believe the writing requirement should be scaled back. This condition, as finalized, imposes no greater—and indeed, may require less—burden on the parties to the written agreement than would otherwise be expected in a commercial transaction involving the exchange or use of cybersecurity technologies or services of this nature between parties, such as a user agreement or purchase order.

Comment: A commenter noted that the OIG safe harbor would require a signed written agreement between a donor and recipient, while the corresponding physician self-referral law exception would require only ''written documentation.'' The commenter recommended that OIG revise the safe harbor to require only written documentation, as opposed to a formal written agreement.

Response: The formality of a signed writing serves as an important safeguard by transparently documenting the parties' donation and formal agreement to any obligations in connection with such donation. However, we are persuaded not to require that the writing be set forth in a single, written agreement. We have revised the writing requirement to permit a ''collection of documents'' approach. To receive safe harbor protection, the general description of the technology and services being provided and the amount of the recipient's contribution, if any, must be set forth in writing and signed by the parties. The terms do not need to be set forth in a single, signed writing, although we believe this approach is a best practice from a compliance perspective. As explained in section III.A.1. of this preamble, some conditions of our safe harbors are different from CMS's final rule by design in light of the different statutory schemes.

o. Cost-Shifting

Summary OIG Proposed Rule: We proposed at proposed paragraph 1001.952(jj)(5) that the donor not shift the costs of the technology or services to any Federal health care program.

Summary of Final Rule: We are finalizing, without modification, the condition at paragraph 1001.952(jj)(4). We received general support for the proposed safeguards in the safe harbor, but we did not receive specific

comments on the proposed prohibition against cost-shifting. Donor Liability

Comment: Several commenters urged OIG to provide guidance on a donor's potential liability for cybersecurity events affecting any recipients of cybersecurity donations. Several commenters, including an organization dedicated to serving chief information officers, chief medical information officers, chief nursing information officers, and other senior health care IT leaders asserted that without some way to protect cybersecurity donors from being held responsible for cybersecurity incidents involving recipients, providers would be reluctant to donate technology or services for fear of the downstream risk they might incur. A few commenters suggested that OIG create protections for donors that safeguard them from risks stemming from cybersecurity incidents experienced by recipients. Another commenter similarly urged OIG to collaborate with OCR to develop a mechanism to limit the donor's liability for cybersecurity events that may occur at the recipient's location. Commenters recommended that OIG create protections for donors that indemnify them from risks stemming from cybersecurity incidents experienced by donors and clarify whether a donor can be indemnified from an OCR action related to a breach when such indemnification provisions are included in the parties' written contract.

Response: Issues relating to downstream liability, indemnification, or other contracting and business tort issues are beyond the scope of this rulemaking. However, we highlight that the safe harbor does not prevent parties from addressing these issues through contracts or other agreements, and we note that the facts and circumstances of any remuneration under such agreements may require separate analysis under the Federal anti-kickback statute.

Comment: One commenter characterized the safe harbor as protecting recipients from liability concerning fines, ransom, and litigation risk.

Response: We agree that the general effect of a cybersecurity donation should help improve a recipient's cybersecurity, thereby potentially reducing the recipient's liability risk for fines, ransom, and litigation stemming from a cyberattack. We clarify, however, that donations protected under this safe harbor do not include monetary remuneration to a recipient, or on behalf of a recipient, for any fines, ransom, or litigation stemming from a cyberattack.

p. Other Comments

Comment: A provider trade association cautioned that hospitals and health systems that donate or subsidize cyber products and services should not use those as a pretext for discouraging or inhibiting the exchange of patient health information between providers.

Response: We note that this safe harbor does not exempt entities and individuals from other applicable State and Federal laws and regulations related to the commenter's concerns about entities' conduct that may inappropriately interfere with, prevent, or materially discourage the exchange of patient health information between providers. The ONC regulation entitled ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' [99] implements provisions of the 21st Century Cures Act [100] (Cures Act) that are designed to address occurrences of information blocking. If patients, providers, or others believe that a health care provider, health IT developer of certified health IT, or health information network or health information exchange is engaging in information blocking, we encourage reporting complaints to HHS through the Report Information Blocking portal (*https://healthit.gov/report-info-blocking*).

Comment: In the preamble to the OIG Proposed Rule related to this safe harbor, we distinguished certain features of cybersecurity donations from EHR donations. A commenter asked OIG to clarify its statement that electronic health record donations ''present a greater risk that [*sic*] one purpose of the donation is for the donor to secure additional referrals from the recipient or otherwise influence referrals or other business generated.'' [101] Specifically, the commenter urged us to clarify that this reference to ''one purpose'' is not intended to introduce the one-purpose test into the rulemaking.

Response: The Federal anti-kickback statute has been interpreted to cover any arrangement in which one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals, and nothing in this final rule changes such interpretation. In other words, offering remuneration to a purchaser or referral source potentially implicates the Federal anti-kickback statute if one purpose is to induce the purchase or referral of Federal health care program business. Donations of EHR, like any other thing of value, constitute remuneration for purposes of the Federal anti-kickback statute. Whether a particular arrangement including a donation of EHR or cybersecurity technology and services violates the statute would depend on the facts and circumstances of such an arrangement, including whether the arrangement complies with a safe harbor.

With respect to the statement the commenter cited from the OIG Proposed Rule, we confirm that we are not introducing the so-called one-purpose test as a condition of the safe harbor at 1001.952(jj).

9. Electronic Health Records Items and Services (42 CFR 1001.952(y))

Summary of OIG Proposed Rule: We proposed changes to the EHR safe harbor at paragraph 1001.952(y), which protects certain arrangements involving the donation of interoperable EHR software or information technology and training services. First, we proposed to amend the safe harbor to clarify that safe harbor protection has always been available for certain cybersecurity software and services, and to expand the safe harbor's potential protection of the donation of software and services related to cybersecurity. Next, we proposed to update the condition at paragraph 1001.952(y)(2) to specify that for software to be ''deemed'' interoperable, it must be certified by a certifying body on the date it is donated. We proposed to modify paragraph 1001.952(y)(3), which already prohibited conduct similar to ''information blocking'' to align with the proposed information blocking definition and related exceptions in the ONC, HHS Notice of Proposed Rulemaking ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (ONC NPRM).[102] We also proposed to eliminate: (i) The condition at paragraph 1001.952(y)(7) that prohibits the donation of equivalent items or services to allow donations of replacement technology; and (ii) the sunset provision at paragraph 1001.952(y)(13) to make the safe harbor permanent. Finally, we proposed to revise the definitions of ''interoperable'' and ''electronic health record'' and add a definition of ''cybersecurity,'' and include all definitions relevant to the safe harbor at proposed paragraph 1001.952(y)(14). We also solicited comments on whether we should modify or eliminate the 15 percent contribution requirement and whether

[99] 85 FR 25642 (May 1, 2020).

[100] 21st Century Cures Act, Public Law 114–255, 130 Stat. 1033.

[101] 84 FR 55737 (Oct. 17, 2019).

[102] 84 FR 7424 (Mar. 4, 2019).

we should expand the scope of protected donors.

Summary of Final Rule: We are finalizing, with modifications, the changes we proposed to paragraph 1001.952(y). We are finalizing our proposal to eliminate the sunset provision and the provision that prohibits the donation of equivalent EHR items and services. We are finalizing the language explicitly protecting cybersecurity software and services and the definition of ''cybersecurity.'' We also are finalizing our revision to paragraph 1001.952(y)(2) to update the deeming provision, with a minor clarification. We are not finalizing paragraph 1001.952(y)(3) related to information blocking or our proposed modifications to the definition of ''electronic health record.'' We are finalizing our modifications to the definition of ''interoperable,'' but we are not including the phrase ''without special effort on the part of the user.'' This final rule also revises paragraph 1001.952(y)(1) to expand the scope of protected donors to certain entities such as accountable care organizations and health systems. The final rule maintains the 15 percent contribution requirement but also includes flexibilities in connection with administering that requirement.

a. Cybersecurity

Summary of OIG Proposed Rule: To clarify that the safe harbor protected cybersecurity software and services related to EHRs, we proposed to amend the introductory language of paragraph 1001.952(y) by including the phrase ''including certain cybersecurity software and services'' and adding the term ''protect.'' We also proposed to include in paragraph 1001.952(y)(14) a definition for ''cybersecurity'' to mean ''the process of protecting information by preventing, detecting, and responding to cyberattacks.''

Summary of Final Rule: We are finalizing, without modification, the introductory language of paragraph 1001.952(y) except for a technical correction by not including the word ''certain.'' We also finalize the definition of ''cybersecurity,'' as proposed.

Comment: We received several comments in support of expressly providing safe harbor protection for certain cybersecurity software and services that protect electronic health records.

Response: We are finalizing protection for cybersecurity software and services, as described in more detail below. We note that, to avoid confusion, we made a technical correction by removing the term ''certain'' in the introductory paragraph of the EHR safe harbor. This change has no substantive effect. This safe harbor protects cybersecurity software and services as long as the donation meet all conditions.

Comment: A commenter expressed concern that the EHR safe harbor's cybersecurity proposal and the separately proposed cybersecurity safe harbor (proposed at paragraph 1001.952(jj)) have significant overlap and could lead to confusion if both were finalized. As such, the commenter suggested that if OIG were to finalize a separate cybersecurity safe harbor, the proposed cybersecurity-related clarifications to the EHR safe harbor would not be necessary. The commenter requested that if OIG were to finalize protection for certain cybersecurity software and services within the EHR safe harbor, the agency clarify that the predominant purpose of the software or service must be cybersecurity associated with the electronic health records. Similarly, another commenter suggested that creating separate safe harbors for electronic health records and cybersecurity is taking a piecemeal approach to tools that must work together for care coordination.

Response: We recognize that there is a certain amount of overlap between the cybersecurity safe harbor finalized in this rule and the EHR safe harbor amended by this final rule. Regardless of this acknowledged overlap, it is useful to clarify in the EHR safe harbor that cybersecurity software and services with the predominant purpose of protecting electronic health records can be protected under the EHR safe harbor provided the donation satisfies all other safe harbor conditions. For example, if one party is donating an EHR system that could be protected under the EHR safe harbor and that EHR system includes cybersecurity functions to protect the electronic health records that might not have appeared to meet the safe harbor's previous standard of being necessary and used predominantly to create, maintain, transmit, or receive electronic health records, then parties seeking safe harbor protection may want to structure the donation arrangement to satisfy the conditions of the EHR safe harbor rather than potentially also looking to the cybersecurity safe harbor. However, the new cybersecurity safe harbor also would remain available for the protection of cybersecurity technology and services if conditions of that safe harbor were met. If, in contrast to the example above, the cybersecurity donation were to include a broader suite of products and services that do not have a predominant purpose to protect the electronic health records (but are used predominantly to implement, maintain, or reestablish effective cybersecurity), then parties seeking safe harbor protection may want to evaluate the arrangement in the context of the standalone cybersecurity safe harbor.

Comment: Some commenters asked us to broaden the scope of cybersecurity protection within the EHR safe harbor to, for example, protect cybersecurity hardware such as network appliances. One commenter asked that the safe harbor protect without exception cybersecurity hardware, software, infrastructure, and services. Another commenter suggested that if the expanded safe harbor does not protect hardware, it should permit donors to place cybersecurity hardware at the recipient's location as long as the donor retains title to or a leasehold interest in the equipment. A commenter noted that in order to protect donors from cyberattacks, the safe harbor should protect the donation of any cybersecurity technology and related services without a contribution requirement to protect any protected health information shared for groups of patients.

Response: We are not expanding this safe harbor to protect additional services or hardware, regardless whether the hardware is donated or loaned to a recipient. The EHR safe harbor is designed to protect donations of EHR software and services, and expressly excludes hardware. By including the word ''protect'' in paragraph 1001.952(y), we are clarifying that the scope of the safe harbor applies to cybersecurity software or information technology and training services that are necessary and used predominantly to protect electronic health records. There is a separate, standalone safe harbor intended to protect broader cybersecurity donations available at paragraph 1001.952(jj). That safe harbor, as finalized in this rule, protects cybersecurity hardware and does not have a contribution requirement.

b. Deeming Provision

Summary of OIG Proposed Rule: We proposed minor modifications to the deeming provision at paragraph 1001.952(y)(2) by changing ''it has been certified by a certifying body'' to read ''it is certified by a certifying body.'' We also proposed to remove reference to ''editions'' of certification criteria to align with proposed changes to the certification program.

Summary of Final Rule: We are finalizing, with modification, our proposal to revise the condition at

paragraph 1001.952(y)(2). We are clarifying that for software to be ''deemed'' interoperable, it must be certified by a certifying body authorized by ONC to certification criteria identified in the then-applicable version of 45 CFR part 170. We are making a technical edit to conform the terminology in our deeming provision to the terminology used in 45 CFR part 170. Specifically, we are removing the phrase ''electronic health record'' preceding ''certification criteria'' because it has been removed from 45 CFR 170 as of June 30, 2020. We are also deleting the word ''editions.''

Comment: Commenters generally agreed with our proposal to clarify that software would be deemed interoperable under the safe harbor if, on the date it is donated, it ''is certified'' by a certifying body authorized by ONC rather than ''has been certified.'' Some commenters had questions about our removal of the phrase ''an edition'' before ''the electronic health record certification criteria'' and inquired whether we should specify that the criteria are the ''latest'' or ''current'' certification criteria.

Response: We agree with comments that we should clarify our intention for the software to be certified to the then-current certification criteria. However, rather than inserting new language the deeming provision will read: ''[f]or purposes of this paragraph (y)(2), software is deemed to be interoperable if, on the date it is provided to the recipient, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to certification criteria identified in the then-applicable version of 45 CFR part 170.'' The version of paragraph 1001.952(y)(2) being finalized maintains nearly identical language from OIG's 2013 final rule addressing the electronic health records safe harbor (2013 EHR Final Rule) except that we changed ''it has been certified by'' to ''it is certified by'' [103] and, as noted above, we removed the phrase ''electronic health record'' before ''certification criteria.'' We note that this latter change does not alter the scope of remuneration protected under this safe harbor; despite removing the phrase in the deeming provision, the safe harbor continues to protect only items and services that are used predominantly to create, maintain, transmit, receive, or protect electronic health records that meet all criteria of the safe harbor.

Comment: A commenter opposed the concept of an ''optional'' deeming provision, asserting that it is critical to require that software be certified by a certifying body authorized by ONC to further support the goal of value-based arrangements.

Response: We agree that interoperability is a critical condition of the EHR safe harbor, but we disagree with the commenter that certification by a certifying body authorized by ONC should be the only way of meeting this standard. This certification provides donors and recipients with assurance that their product is interoperable for purposes of this safe harbor, but such certification is not a requirement for safe harbor protection.

Comment: A commenter suggested that the proposed change to the deeming provision creates compliance uncertainty in the context of an ongoing software donation. In particular, the commenter was concerned that the proposed wording change would mean that any time after the initial donation the EHR software loses its certification, the continued provision of the software including maintenance would implicate the fraud and abuse laws. Other commenters supported the proposal to require software to be certified at the time it is provided to a recipient, with a commenter noting that any updates to donated systems should also be certified to the most recent standards. A commenter asked that physicians not participating in the Quality Payment Program be granted a 5-year grace period under the interoperability deeming provision so that their donated EHR software need only be certified to the 2015 edition.

Response: The deeming provision in paragraph 1001.952(y)(2) is optional. Certification of donated software by a certifying body authorized by ONC is not required to meet the terms of the safe harbor; the safe harbor requires that, to receive protection, the software must be interoperable at the time it is provided to the recipient. To the extent physicians or other health care providers are seeking protection of donated EHR items and services under the safe harbor, the donated EHR software need only be interoperable (as defined at paragraph 1001.952(y)(14)(iii)) to satisfy the condition at paragraph 1001.952(y)(2).

If an EHR item or service loses its certification, it would no longer satisfy the deeming provision. Therefore, new donations of such EHR items or services, including updates and patches of the software would not satisfy the safe harbor's deeming provision. However, if the EHR items or services were still interoperable (as defined at paragraph 1001.952(y)(14)(iii)), then the safe harbor would protect continued donation of such software and services, including patches, as long as all other conditions are met.

c. Information Blocking

Summary of OIG Proposed Rule: We proposed modifying paragraph 1001.952(y)(3) by incorporating a reference to the information blocking definition and related exceptions in 45 CFR part 171. We solicited comments on this approach.

Summary of Final Rule: We are not finalizing the proposed modification to paragraph 1001.952(y)(3) and instead are deleting this condition from the safe harbor.

Comment: We received a number of comments about our proposal to incorporate the ''information blocking'' prohibition from the 21st Century Cures Act (Cures Act) [104] or the ONC NPRM into the safe harbor at paragraph 1001.952(y)(3). While commenters did not necessarily disagree that information blocking should be prohibited, commenters raised a number of questions and concerns regarding how such a provision would work in a safe harbor. For example, although we received from commenters support for our proposal to update the safe harbor to include a condition that would preclude safe harbor protection for arrangements that lead to ''information blocking'' as that term is used in the Cures Act, a number of commenters expressed concern about relying on the ONC NPRM, which was not yet final. Commenters were particularly concerned about the array of exceptions to the definition of ''information blocking'' and incorporation of the definition of ''electronic health information'' as proposed in the ONC NPRM.

Some commenters asked that we clarify which party is responsible to ensure that information blocking does not occur. For example, some commenters noted that a donor cannot control what happens to software after it is donated. Similarly, several commenters recommended removing or revising the condition that a donor (or any person on a donor's behalf) does not engage in a practice constituting information blocking, explaining that a vendor may engage in information blocking without the donor's knowledge. Commenters expressed contrasting opinions about the proposed knowledge standard, with some commenters recommending that it apply to both health care providers and health plans that voluntarily use the safe

[103] 78 FR 79202 (Dec. 27, 2013).

[104] 21st Century Cures Act, Public Law 114–255, 130 Stat. 1033.

harbor to protect donations under this safe harbor, while others recommending that health plans be subject to the ''knows, or should know'' standard because health plans are not health care providers and do not have direct patient care responsibilities.

Another commenter noted that if a determination of information blocking against either a donor or recipient occurs at some time after a donation, the recipient may be vulnerable to unexpected costs or lose access to its health information technology if the arrangement suddenly ends.

Another commenter suggested that, rather than including a prohibition on information blocking (as such term is defined in the Cures Act or in 45 CFR part 171) as a safe harbor condition, OIG should assume that information blocking will not be tolerated and will be enforced through other authorities.

Response: Based on the comments and assessing the final rule published by ONC, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (ONC Final Rule),[105] we are not finalizing the proposed information blocking condition, and we are removing the existing paragraph 1001.952(y)(3), which prohibits the donor or any person on the donor's behalf from taking any action to limit or restrict the use, compatibility, or interoperability of the donated EHR items or services. This condition, when originally implemented in OIG's 2006 final rule creating the electronic health records safe harbor (2006 EHR Final Rule),[106] was intended to help ensure that transfers of health information technology will further the policy goal of fully interoperable health information systems and will not be misused to steer business to the donor.[107] The 2013 EHR Final Rule also explained that the Department was considering other policies to improve interoperability, and noted that those policy efforts are better suited than this anti-kickback statute safe harbor to consider and respond to evolving functionality related to the interoperability of electronic health record technology.[108] At that time, the Department had few other authorities to directly address information blocking. However, there are now other enforcement authorities designed to address information blocking. For example, the Cures Act gave ONC and OIG more direct authority to address information blocking.[109] Additionally, CMS has separate authority to require certain providers and suppliers to attest that they have not knowingly and willfully limited or restricted the compatibility or interoperability of their certified electronic health record technology.[110]

In addition, the Cures Act and the ONC Final Rule recognize that certain practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information may nonetheless be reasonable and necessary. That is why the Cures Act directed the Secretary to identify exceptions to the definition of ''information blocking.'' The ONC Final Rule implements eight exceptions that apply to practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information provided the practice meets the conditions of an exception. However, the condition at paragraph 1001.952(y)(3) as implemented by the 2006 EHR Final Rule conditioned safe harbor protection on a party not taking ''any action to limit or restrict the use, compatibility, or interoperability'' of the donated EHR items or services. The condition did not account for actions that may be reasonable and necessary, such as implementing privacy and security measures.

Recognizing these developments, we agree with the commenter that these new authorities are better suited than a safe harbor condition to deter information blocking and penalize individuals and entities that engage in information blocking. We also agree with commenters that a recipient is unlikely to have the capabilities to determine whether a donor (or someone on the donor's behalf) engaged in information blocking, which includes a level of intent set by statute, or met an exception to information blocking as set forth in the ONC Final Rule.

Given these potential issues with the proposed modifications to paragraph 1001.952(y)(3) and limitations of the original condition in paragraph 1001.952(y)(3) discussed previously, the condition may no longer be an effective way to achieve the policy goals that served as the original basis for this condition. Removing the condition at paragraph 1001.952(y)(3) is responsive to commenters that had questions about the scope of information blocking practices, how OIG would determine the party responsible, how the information blocking knowledge standard in the Cures Act and ONC Final Rule would be assessed in context of this safe harbor, and how the condition would apply to parties that may not be subject to the information blocking provision in section 3022 of the Public Health Service Act (PHSA).

We emphasize, however, that we are maintaining the interoperability condition in paragraph 1001.952(y)(2). We believe this condition and the optional deeming provision will ensure that donations of EHR items and services that meet the conditions of this safe harbor further the Department's policy goal of an interoperable health system and prevent donations being made with the intent to lock in referrals by limiting the flow of electronic health information.

OIG remains committed to taking action against individuals and entities that engage in information blocking, using specific authorities to do so. Separate from this rule, OIG published a notice of proposed rulemaking related to information blocking enforcement.[111] That proposed rule, among other things, proposes the basis and procedures for information blocking enforcement. As stated in that proposed rule, addressing the negative effects of information blocking is consistent with OIG's mission to protect the integrity of HHS programs as well as the health and welfare of program beneficiaries.[112]

d. Sunset Provision

Summary of OIG Proposed Rule: We proposed to eliminate the sunset provision at paragraph 1001.952(y)(13). As an alternative, we also proposed an extension of the sunset date for the final rule.

Summary of Final Rule: We are finalizing this proposal by deleting the sunset provision at paragraph 1001.952(y)(13).

Comment: We received nearly universal support for removing the sunset provision in paragraph 1001.952(y)(13), which requires that all protected EHR donations must occur on or before December 31, 2021. Commenters asserted that the elimination of the sunset date would provide certainty for the ongoing protection of donations of EHR items and services. One commenter who generally supported making the safe harbor permanent recommended that OIG delay doing so until the ONC NPRM is finalized and available for stakeholder consideration.

Response: We agree that eliminating the sunset provision provides certainty,

[105] 85 FR 25642 (May 1, 2020).

[106] 71 FR 45110 (Aug. 8, 2006).

[107] 71 FR 45127.

[108] 78 FR 79214 (Dec. 27, 2013).

[109] Sec. 4002 and 4004 of the Cures Act.

[110] *See* 81 FR 77008, 77028 (Nov. 4, 2016).

[111] 85 FR 22979 (Apr. 24, 2020).

[112] *Id.*

and we are finalizing our proposal to make this safe harbor permanent and, as we note above, the ONC Final Rule was issued on May 1, 2020.

e. Contribution Requirement

Summary of OIG Proposed Rule: We did not propose specific changes to the 15 percent contribution requirement at paragraph 1001.952(y)(11). Instead, we considered and solicited comments on three alternatives: (i) Eliminating or reducing the percentage of the contribution required for small or rural practices; (ii) reducing or eliminating the 15 percent contribution requirement in this safe harbor for all recipients; or (iii) modifying or eliminating the contribution requirement for updates to previously donated EHR software or technology.

Summary of Final Rule: We are retaining the 15 percent contribution requirement at paragraph 1001.952(y)(11) but removing the requirement that payment of the contribution be made in advance for updates to existing EHR systems. To make this modification, we have added new paragraphs at 1001.952(y)(11)(i) and (ii). Paragraph 1001.952(y)(11)(i) describes that contributions for initial and replacement EHR items and services must be made in advance of the donation and contributions for updates to previously donated EHR item and services need not be paid in advance. Paragraph 1001.952(y)(11)(ii) is the new location of the condition that the donor does not finance the recipient's contribution amount; it does not include any substantive changes.

Comment: A large number of commenters on this topic recommended that we remove the 15 percent contribution requirement for all donations and for all recipients. Commenters provided several reasons to remove the contribution requirement (paragraph 100.952(y)(11)). For example, some commenters suggested that this requirement restricts the use of EHRs with interoperable capabilities; that this is not an effective deterrent to inappropriate EHR donations; and that the percentage is an arbitrary amount that limits the use of important patient tools. Commenters noted that any transition to improve EHR technology can streamline physicians' workflows; alleviate burdens; allow physicians to spend more time with their patients; and allow (assuming that the donated technology is truly interoperable) the sharing of patient records with near equal ease with other providers using certified EHR technology. Some commenters questioned whether a recipient contribution reduces the risk of steering and inappropriate referrals.

Commenters noted that the donation of EHR technology can be beneficial to recipients who may be unsatisfied with their EHR platform but lack the resources to transition to a new platform. A commenter noted that the contribution requirement may be an unreasonable constraint on how health systems and hospitals finance the needed infrastructure to implement new value-based payment models and promote the coordination of care. Commenters cited the added burden involved in setting the contribution amount in writing and the necessary, ongoing monitoring to ensure compliance. Commenters also highlighted that eliminating the requirement would align this safe harbor with the proposed cybersecurity safe harbor at paragraph 1001.952(jj) for which OIG did not propose to include a contribution requirement.

Commenters that supported eliminating the contribution requirement as a condition to this safe harbor still supported allowing the donor to require a contribution. For example, a commenter suggested that any contribution requirement should be left up to market forces and negotiation between the parties. Another commenter stated that the contribution amount should be at the discretion of the donor as long as the donor consistently and fairly applies their policy to all recipients. Finally, a commenter suggested that the contribution requirement should only be eliminated if the scope of protected donors remains the same.

Response: We understand the donation recipients' desires to eliminate the 15 percent contribution requirement. However, after careful consideration, we continue to believe that the contribution requirement is an important safeguard against fraud and abuse in light of the specific risks of inappropriate generation of referrals presented by donation of EHR items and services. When recipients of valuable remuneration have some responsibility to contribute to the cost of the items or services, they are more likely to make economically prudent decisions and accept only what they need or will use. As we note below, however, we are adding some flexibilities in connection with administering the contribution requirement.

Comment: Some commenters raised concerns about eliminating the contribution requirement. For example, one commenter believed that physician adoption and use of an EHR system is improved when they have a certain level of buy-in and share in the financial cost. Similarly, other commenters suggested that 15 percent represents a fair contribution amount, serves as a reasonable safeguard to reduce wasteful spending, and that it is important for recipients to have a stake in the purchased technology.

Response: We agree with commenters that the contribution amount is fair and provides a reasonable safeguard. For these and other reasons discussed in this final rule, we are maintaining the 15 percent contribution requirement.

Comment: We received support for eliminating the recipient contribution requirement for at least a subset of recipients. Some commenters specifically referenced removing the requirement for all physicians. A majority of these commenters recommended removing the contribution requirement for at least small and rural providers or providers serving underserved populations. Some commenters expressed concern about how we would define ''small'' or ''rural'' if we limited the exception to those classes of individuals or entities. A number of commenters requested that the concept of ''small and rural'' practices be defined broadly and to specifically include free clinics, charitable clinics, and charitable pharmacies. We also received a recommendation to adopt the definition of ''small practice'' used in the CMS Quality Payment Program.[113] Various commenters requested that the contribution requirement be eliminated for safe harbor protection applicable to Indian health care provider recipients. We also received comments regarding other potential recipients for whom the contribution requirement may be a financial burden, such as critical access hospitals, disproportionate share hospitals, and essential hospitals. A commenter recommended that ''underserved practices'' should be defined as those in: (i) Medically underserved areas, as designated by the Secretary under section 330(b)(3) of the PHSA; (ii) primary health care geographic health professional shortage areas, as designated by the Secretary under section 332(a)(1)(A) of the PHSA; or (iii) a critical access hospital. A commenter recommended defining ''rural practices'' as those located in rural areas, as defined in the local transportation safe harbor at paragraph 1001.952(bb).

Commenters noted that for cash-strapped entities, the contribution requirement is a financial burden. For example, certain tribal organizations

[113] 42 CFR 414.1305.

highlighted the financial burden of the EHR safe harbor's contribution requirement for Indian health care providers and asserted any contribution requirement may inappropriately divert funding away from patient care. Some commenters noted that the 15 percent contribution can be a significant barrier for physician adoption of EHR technology, even for practices that may not qualify as small or rural practices. Some commenters noted that the burden is not only in the actual cost of the contribution but also the administrative tasks associated with tracking and calculating the 15 percent.

Response: As we explain above, we are retaining the 15 percent contribution requirement for all recipients seeking protection for EHR donations under the EHR safe harbor. We agree with the commenters who expressed concern about defining subgroups of entities to exempt from this requirement. Even if we were to adopt certain definitions existing in other regulations or definitions suggested by commenters, some of those designations can change over time (*e.g.,* a physician practice may qualify as a ''small practice'' at some but not other points in time depending on staffing changes), which could create confusion about implementation of the contribution requirement and raise corresponding safe harbor compliance concerns. In addition, the fraud and abuse risks associated with EHR donations apply regardless of the geography or size of the donation recipient. If cost is a barrier for a particular recipient, the recipient could request an advisory opinion about an arrangement without a 15 percent contribution requirement.

Comment: In response to our solicitation of comments on possibilities to reduce any uncertainty and administrative burden associated with assessing a contribution for each update, some commenters addressed other aspects of the contribution requirement. For example, a commenter expressed concern about the requirement that contributions must be made in advance. This commenter noted that recipients may unintentionally fall outside the safe harbor due to inadvertent late payments and requested that OIG add a remedy period for mistakes to be corrected without losing safe harbor protection. Another commenter recommended eliminating the requirement that fees be collected prior to the receipt of services and recommended instead to require a commercially reasonable collections process.

Response: Consistent with our solicitation of comments on uncertainty and administrative burden, and our statement in the OIG Proposed Rule that we were considering modifying the contribution requirement as it relates to updates, we are removing the requirement that payment of the contribution be made in advance for updates to existing EHR systems. We recognize that updates may need to take place quickly to remedy security or other problems in an EHR system, and we understand the commenter's concern about inadvertent late payments under such circumstances. We believe it is reasonable and does not create additional risk to bill a recipient for its contribution after providing the update. The safe harbor does not require a specific billing method. In other words, a donor could choose to bill a recipient separately for each update or could bill the recipient monthly or quarterly to combine the contribution claims for all updates during a select period of time.

We are not, however, removing the requirement that contributions be made in advance of an initial donation (including the donation of a replacement system). Parties seeking safe harbor protection can effectively plan for an initial donation, with all expenses known up front, so that there is not the same administrative burden or uncertainty that parties may experience when invoicing for periodic updates, and, therefore, there is less risk of inadvertent late payments. Because the need for safe harbor protection would not be triggered until the initial donation happens, and the parties have the ability to wait to make the donation until the contribution is paid, we are not adopting a cure period for late payments associated with initial or replacement donations.

Comment: A number of commenters asked that if OIG retains a contribution requirement on the initial EHR donation, the contribution requirement be eliminated for updates to the original donation. Commenters noted that the updates may ensure that the donation continues to function as needed and to meet current Federal standards for data exchange. In contrast, a commenter recommended OIG consider retaining a contribution requirement only for the provision of replacement technology while eliminating it for the original donation and any updates to that original system.

Response: As explained above, we are retaining the contribution requirement for updates but will no longer require that the contribution for updates be made in advance. We recognize that updates are crucial for the continuing functionality of a system. However, we do not think it is feasible to retain a contribution requirement for certain donations and eliminate it for others. If we were to adopt that policy, parties might structure donations to game the difference between donation types. For example, if a recipient were not required to contribute to updates, parties could structure the ''initial'' donation to consist of a functionality with a small cost and consequently a small required contribution, with the most valuable functionality deemed to be an ''update'' with no required contribution. We believe the risk posed by such arrangements would reduce the effectiveness of the contribution requirement as a safeguard against fraud and abuse. For this reason, all donations protected by this safe harbor require a recipient contribution.

Comment: A commenter requested that if a contribution requirement is retained, the parties use either the fair market value or the underlying cost of the donation as the base amount from which the contribution is calculated. The commenter believed that this would reduce the administrative burden of compliance, which might allow smaller providers to donate protected EHR.

Response: The relevant standard in the safe harbor is that ''the recipient pays 15 percent of the donor's cost for the items and services.'' We did not propose to change this cost-based standard and are not finalizing any change. In 2006, when we initially finalized the EHR safe harbor, we provided an explanation about calculating the cost of these items and services.[114] The cost should be clear when a donor is purchasing an item or service from a vendor. However, we recognized some software or other modules may be internally developed. We recommended that parties should use a reasonable and verifiable method for allocating costs and maintain documentation of such allocation. We explained there, and maintain here, that the method for allocating costs would be scrutinized to ensure that they do not inappropriately shift costs in a manner that provides an excess benefit to the recipient or results in the recipient effectively paying less than 15 percent of the donor's true cost for the technology.[115]

Comment: A commenter encouraged HHS to study whether the 15 percent recipient contribution requirement has in fact prevented some or many physicians practices from adopting EHR technology, whether the safe harbor has produced lasting partnerships and ongoing incentives to use technology, and whether technology donations

[114] 71 FR 45133 (Aug. 8, 2006).

[115] 71 FR 45133 (Aug. 6, 2006).

potentially protected by the safe harbor have resulted in market consolidation or channel capture that has led to increased costs for consumers.

Response: Any decision by HHS to study the effectiveness or other impact of the safe harbor and its conditions is outside the scope of this rulemaking.

Comment: A commenter recommended not requiring the 15 percent contribution for cybersecurity donations under this safe harbor. The commenter noted that some organizations will permit practices to use their EHR systems only if the practice has certain cybersecurity protections, and thus the commenter suggested that the party requiring the cybersecurity protection should pay any costs associated with it.

Response: We are not finalizing separate requirements for different types of donations within this safe harbor. If a party seeks to protect a donation of cybersecurity software or services under the conditions of the EHR safe harbor, then a contribution is required. However, parties that seek to protect a cybersecurity donation without a recipient contribution could structure the donation to meet the safe harbor for cybersecurity technology and related services at paragraph 1001.952(jj).

f. Equivalent Technology and Scope of Protected Donations

Summary of OIG Proposed Rule: We proposed to delete the condition that prohibits the donation of equivalent items or services at paragraph 1001.952(y)(7) to allow donations of replacement EHR technology.

Summary of Final Rule: We are finalizing this proposal by deleting paragraph 1001.952(y)(7).

Comment: Commenters broadly supported removing the safe harbor condition at paragraph 1001.952(y)(7) that prohibits the protection of EHR donations if a recipient possesses items or services equivalent to those to be donated. Commenters provided a number of reasons for their support of the elimination of this condition, highlighting that some physician practices may be working with an EHR system that no longer meets their needs, is outdated, or is otherwise substandard because they cannot afford the full cost to replace the system. A commenter recommended that OIG eliminate this condition but require a documented rationale for a need for replacement technology.

Response: We agree with the commenters and are finalizing our proposal to remove the condition at paragraph 1001.952(y)(7) that prohibits the donation of equivalent items and services. We recognize that there may be valid business or clinical reasons for a recipient to replace an entire system rather than update existing technology. Under this safe harbor, replacement technology is treated the same as a new donation and would need to meet all conditions of the safe harbor to receive protection. For example, a recipient of replacement technology would be required to pay at least 15 percent of the donor's cost for the items and services before receiving the items and services. We believe that treating a donation of replacement technology the same as a new donation strikes an appropriate balance by making necessary replacements financially feasible for recipients while maintaining safeguards to limit the risk of recipients inappropriately soliciting or accepting unnecessary technology.

Comment: Commenters recommended revisions to the language related to the scope of protected donations. For example, a commenter requested that the safe harbor be expanded to include training, maintenance, and upgrades of EHRs. Similarly, a commenter recommended revising the language to items and services in the form of software, other information technology, and related services, including implementation, training and support services. A commenter asked whether the safe harbor would still potentially protect the ''services'' listed as examples in the 2006 EHR Final Rule such as connectivity, broadband, wireless, clinical support, information services related to patient care, and maintenance. Another commenter was concerned that the safe harbor protected only donations of technology that have been certified by ONC. Other commenters asked for a significantly expanded scope of potentially protected donations including but not limited to: (i) Hardware; (ii) technology related to information sharing; (iii) cloud-based items and services; (iv) practice management and revenue cycle systems and services; (v) clearinghouse services; and (vi) industry-supported data collection and analytics.

Response: As we note elsewhere in this section, we are removing the condition at 1001.952(y)(7) from the safe harbor to protect donations of replacement technology and clarifying the safe harbor to explicitly protect cybersecurity software and services if all safe harbor conditions are satisfied. The safe harbor already could protect some of the items or services suggested by commenters, such as maintenance and training. The modifications to this safe harbor as finalized, do not narrow the scope of items or services that could receive safe harbor protection; the examples listed in the 2006 EHR Final Rule could still receive safe harbor protection under the amended safe harbor finalized in this rule.[116] We also wish to highlight, as we explain elsewhere, that the safe harbor does not require that donated software is certified as interoperable by a certifying body authorized by ONC; the safe harbor requires that donated software is interoperable. Per the terms of the ''deeming provision,'' certified software is deemed to be interoperable. The scope of electronic health record items and services protected by this safe harbor and the optional deeming provision give donors and recipients appropriate flexibility to determine which items and services should be donated given their circumstances. For example, long-term care and post-acute care recipients may need different types of electronic health record items and services than a physicians group practice needs.

We did not propose and thus are not finalizing in this safe harbor any expansion that would protect donated hardware. For any of the other software or services for which commenters requested safe harbor protection, the standard remains as we proposed, *i.e.,* that the items or services must be necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records. For example, some technology related to information sharing could meet this standard, such as the donation of software or services related to application programming interfaces (APIs) used to support the exchange of

[116] Specifically, we stated in the 2006 EHR Final Rule that we interpret '' 'software, information technology and training services necessary and used predominantly' for electronic health records purposes to include the following, by way of example: Interface and translation software; rights, licenses, and intellectual property related to electronic health records software; connectivity services, including broadband and wireless internet services; clinical support and information services related to patient care (but not separate research or marketing support services); maintenance services; secure messaging (*e.g.,* permitting physicians to communicate with patients through electronic messaging); and training and support services (such as access to help desk services). We interpret the scope of covered electronic health records technology to exclude: Hardware (and operating software that makes the hardware function); storage devices; software with core functionality other than electronic health records (*e.g.,* human resources or payroll software, or software packages focused primarily on practice management or billing); or items or services used by a recipient primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations. Furthermore, the safe harbor does not protect the provision of staff to recipients or their offices. For example, the provision of staff to transfer paper records to the electronic format would not be protected.'' 71 FR 45125.

electronic health information. Parties seeking to rely on the safe harbor need to analyze the EHR donation arrangement to ensure that it squarely meets all of the safe harbor's conditions.

g. Protected Donors

Summary of OIG Proposed Rule: We solicited comments on either removing the restrictions on protected donors in paragraph 1001.952(y)(1)(i) or revising the paragraph to protect donations from entities with indirect responsibilities for patient care, such as health systems or accountable care organizations that are neither health plans nor submit claims for payment.

Summary of Final Rule: This final rule expands the scope of protected donors to certain entities that are comprised of the types of individuals or entities listed as protected donors in paragraph 1001.952(y)(1)(i)(A). To effectuate this change, we added paragraphs 1001.952(y)(1)(i)(A) and (B), which describe the entities previously considered protected donors to include the new entities considered protected donors as established by this final rule.

This final rule expands the scope of protected donors to certain entities that are comprised of the types of individuals or entities listed as protected donors in paragraph 1001.952(y)(1)(i)(A), as described in more detail below.

Comment: We received a range of comments in response to our suggestion that we may consider expanding the scope of protected donors. At one end of the spectrum, we received a suggestion not to change the scope of protected donors at all. At the other end, a commenter stated that the safe harbor should protect donations from all entities. However, the most common recommendation from commenters on this topic was to expand the scope of protected donors to entities with indirect responsibility for patient care such as health systems, accountable care organizations, clinically integrated entities, and other entities that bear financial risk in patient outcomes. Commenters noted that these types of entities have little incentive to abuse the safe harbor and that protecting donations from certain entities that do not bill the Federal health care programs would facilitate expanded use of technology that may reduce the cost of care and increase care coordination. We also received a request to continue excluding laboratories from the scope of protected donors.

Response: We agree with commenters who recommended expanding the scope of protected donors to include entities comprised of the types of entities currently covered as protected donors (*e.g.,* parent companies of hospitals, health systems, and accountable care organizations). We see little added risk to protecting donations of interoperable electronic health records software or information technology and training services by entities such as health systems or accountable care organizations. These entities may have financial risk for patient outcomes and generally do not directly receive referrals. However, we believe the risk is too high to expand safe harbor protection to donations from all entities. We continue to have concerns about protecting EHR donations made by laboratories or manufacturers or suppliers of items. Accordingly, donations made by these entities will continue to be ineligible for protection under the EHR safe harbor.

Comment: A commenter asked whether the safe harbor protects donations from pharmaceutical manufacturers that participate in Federal health care programs.

Response: Pharmaceutical manufacturers generally do not bill Federal health care programs and are not comprised of entities that bill Federal health care programs and therefore are not protected donors under the safe harbor. While we recognize that some manufacturers have implemented programs that include more direct contact with patients and payors, the concerns we expressed in the preamble to the 2006 EHR Final Rule [117] continue to exist today. If a manufacturer that operates its business in a way that it believes would meet the terms of this safe harbor has questions about whether any donation would be protected by the safe harbor or present a low risk of fraud and abuse under the Federal anti-kickback statute, the advisory opinion process remains available.

Comment: A commenter requested that the safe harbor protect donations made only by donors that provide EHR access to pharmacists. The commenter stated that some health information technology systems block pharmacists' visibility into relevant clinical information from other health care providers.

Response: The safe harbor does not limit the scope of protected donors to donors that grant EHR access to a specified range of providers or suppliers. However, for a donation to be protected, it must be interoperable and should not inappropriately interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (*e.g.,* inappropriately limit visibility to relevant clinical information). To the extent that patients, providers, or others believe that a health care provider, health IT developer of certified health IT, health information network, or health information exchange is engaging in information blocking, we encourage reporting complaints to HHS through the Report Information Blocking portal, which is available at *https://healthit.gov/report-info-blocking.*

Comment: A commenter requested that the EHR safe harbor protect donations made by multiple donors for different types of technology to a single recipient, as long as the technology meets the interoperability requirements. The commenter recommended the safe harbor specifically protect the donation of supplemental, nonequivalent EHR applications that supplement a recipient's current EHR system and noted that such applications could come from different donors. The commenter further proposed the safe harbor require a clinical necessity analysis for ''add-on'' EHR applications in addition to replacement technology.

Response: Nothing in the amended safe harbor, as it is being finalized, would prevent safe harbor protection of donations of ''add-on'' EHR applications or donations from multiple donors. Protection offered by this safe harbor is not limited to EHR products that include within a single product a sufficiently comprehensive array of functions to constitute an ''EHR system.'' Instead, as explained in the 2006 EHR Final Rule, the safe harbor also applies to donations of software that serve a specific function related to electronic health records, such as interface and translation software and secure messaging. In some instances, those functions may be part of a larger EHR software product, or they may be implemented via standalone software that interacts with a provider's electronic health record system. If each donation squarely satisfies the requirements of the amended safe harbor—including the requirement that the software is or the information technology and training services are

[117] 71 FR 45128 (''We have not included as protected donors pharmaceutical . . . manufacturers. . . . These entities do not provide health care items or services to patients or submit claims for those services. Our enforcement experience demonstrates that unscrupulous manufacturers have offered remuneration in the form of free goods and services to induce referrals of their products. Given this enforcement history, and the lack of a direct and central patient care role that justifies safe harbor protection for the provision of electronic health records technology, we are not including manufacturers as protected donors. We believe there is a substantial risk that, in many cases, manufacturers' primary interest in offering technology to potential referral sources would be to market their products.'')

necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records—such donations could be protected regardless of whether the technology is donated by one or multiple donors.

We did not propose and thus are not finalizing a condition that requires a clinical necessity analysis of donations. Such condition would not be necessary in the safe harbor given the totality of its conditions.

h. Definitions

i. Electronic Health Record

Summary of OIG Proposed Rule: We proposed to modify the definition of ''electronic health record'' in paragraph 1001.952(y)(14)(iv) to mean: ''a repository of electronic health information that: (A) Is transmitted by or maintained in electronic media; and (B) relates to the past, present, or future health or condition of an individual or the provision of healthcare to an individual.''

Summary of Final Rule: We are not finalizing the proposed definition of electronic health record and instead retain the previous definition. This final rule moves the definition of ''electronic health record'' to paragraph 1001.952(y)(14)(iv).

Comment: Several commenters expressed general support for our proposed revision to the definition of ''electronic health record,'' particularly to the extent that the definition would align with the definition included in the Cures Act. However, a number of commenters were concerned about our proposal to use the term ''electronic health information'' as the ONC NPRM proposed to define such term. Commenters asserted that the regulatory definition proposed by ONC is overly broad and may extend far beyond what Congress intended under the Cures Act. For example, a commenter argued that under the proposed definition a patient's computer or mobile telephone could be considered an electronic health record if the patient obtained a copy of their health record through electronic transmittal. Commenters also made several suggestions to limit the scope of ''electronic health information.''

Response: As we stated in the OIG Proposed Rule, we did not intend for our proposed modifications to the definition of ''electronic health record'' to make a substantive change to the scope of protection.[118] We thank commenters for highlighting the complexities that our changes inadvertently might have introduced. To remain true to our intent, we are not finalizing any proposed changes to the definition of ''electronic health record.'' We will retain the existing definition in the safe harbor, which appears at paragraph 1001.952(y)(14)(iv).

Comment: A commenter recommended that the definition of ''electronic health record'' should be standardized across all Federal regulations, as permitted by the relevant statutory framework. However, the commenter expressed doubt that changing the definition of ''electronic health record'' as OIG proposed would keep up with a dynamic redefinition of how electronic health care is provided.

Response: A suggestion to standardize definitions across Federal regulations is outside the scope of this final rule. As noted above, we are not finalizing any changes to the definition.

Comment: A commenter recommended that OIG define the parameters of the EHR safe harbor to ensure that the scope of covered technology under the ''electronic health record'' definition protects products beyond those that are standalone EHRs (*e.g.,* products that connect to, amplify the capabilities of, or leverage the data in EHRs to promote coordination and management of care). According to the commenter, there are emerging technologies that leverage data in EHRs without creating new records and enable patients to leverage technology to maintain longitudinal records. To modernize the safe harbor to accommodate these developments, a commenter asked that OIG clarify that the term ''repository'' in the current and proposed definition of EHR is not limited to existing models of EHR. The commenter also recommended that OIG delete ''predominantly'' from the safe harbor or otherwise broaden the remuneration protected by the safe harbor by adding the italicized words in the following phrase from the EHR definition: ''software or IT functionality necessary and used predominantly to *support or improve* [italics added] the creation, maintenance, transmission, receipt *or use* of EHR.''

Response: By proposing to revise the definition of ''electronic health record,'' we did not intend to change the scope of protection under the safe harbor. We are retaining the existing definition of ''electronic health record'' and are not adopting the commenter's suggestion. Emerging technologies that leverage EHR data may be protected by the safe harbor. The term ''repository'' carries its common meaning: A place where something such as data can be stored and managed. If emerging technologies are necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, and all of other conditions of the safe harbor are met, then donations of such technologies would be protected.

Donations of software or information technology services do not need to be necessary and used predominately for all five functions listed in paragraph 1001.952(y)(1) to be protected. Rather, the software or information technology services must meet at least one of the five functions. For example, if software is not used to create an electronic health record but is necessary and used predominately to transmit electronic health records, donations of such software may be protected by this safe harbor if all other conditions are met. If an entity has questions about whether specific technology donations would be protected by the safe harbor or present a low risk of fraud and abuse under the Federal anti-kickback statute, the advisory opinion process remains available.

Comment: A commenter supported the current definition of ''electronic health record'' rather than the proposed revisions to the definition. However, the commenter asked OIG to further clarify this definition so that it would include a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting that automates and streamlines the clinician's workflow.

Response: We are adopting the recommendation to retain our current definition of ''electronic health record.'' We agree that the commenter's example of a longitudinal electronic record appears to meet this definition. However, we recommend that parties conduct their own analysis of the particular facts and circumstances of any arrangement as applied to the definition. The advisory opinion process remains available for parties that seek an individualized determination.

ii. Interoperable

Summary of OIG Proposed Rule: We proposed to update the definition of the term ''interoperable'' to align with the statutory definition of ''interoperability'' added by the Cures Act to section 3000(9) of the PHSA and move it to paragraph 1001.952(y)(14)(iii). We proposed to define ''interoperable'' as able to ''(A) securely exchange data with, and use data from other health information technology without special effort on the part of the user; (B) allow for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (C)

[118] *See* 84 FR 55742 (Oct. 17, 2019).

does not constitute information blocking as defined in 45 CFR part 171.''

Summary of Final Rule: We are finalizing, with modifications, an updated definition of ''interoperable'' in paragraph 1001.952(y)(14)(iii). We are removing the phrase ''without special effort on the part of the user'' in paragraph 1001.952(y)(14)(iii)(A), and we are not finalizing proposed paragraph 1001.952(y)(14)(iii)(C) that would have incorporated the information blocking regulations in the definition of interoperability.

Comment: We received general support for our effort to update the definition of ''interoperable.'' However, some commenters asked for further clarification of the phrase ''without special effort on the part of the user.''

Response: First, we are finalizing the first two proposed criteria of the ''interoperability'' definition except, as explained below, we are removing the phrase ''without special effort on the part of the user.'' We are removing the third criterion we proposed in the ''interoperable'' definition: ''[d]oes not constitute information blocking as defined in 45 CFR part 171.'' That criterion raises similar issues that we discussed in section 9.c above regarding the information blocking condition at former paragraph 1001.952(y)(3). Removal of that condition is consistent with our rationale described in more detail above.

We had proposed for the first prong of the definition of ''interoperable'' that it mean able to ''[s]ecurely exchange data with and use data from other health information technology without special effort on the part of the user.'' While the phrase ''without special effort on the part of the user'' is used in the definition of ''interoperability'' in the Cures Act,[119] the phrase ''without special effort'' also is used in conditions of certification in the Cures Act.[120] As we make clear above in section 9.b, while software certified by ONC is ''deemed'' to be interoperable, certification is not required for safe harbor compliance. Therefore, to avoid any implication that we are incorporating a certification requirement into the definition of ''interoperable'' as it is used in this safe harbor, we are removing the reference to ''without special effort on the part of the user.''

Comment: A commenter expressed concern about the Federal Government's definition of ''interoperability,'' as defined in the ONC NPRM, which the commenter believes inappropriately focuses solely on high volumes of data transferred or access to every piece of health information ever collected. The commenter asserted that we should prioritize the transfer of and access to secure, meaningful data in order to avoid: (i) Confusing patients who lack context; and (ii) overburdening physicians with irrelevant information.

Response: First, as we note elsewhere in this section, we are revising this safe harbor such that the definition of ''interoperable'' no longer refers to the definition proposed in the ONC NPRM. Second, interoperability of donated EHR items and services is an important condition of the safe harbor. The definition adopted in this final rule states that ''interoperable'' means ''able to'' securely exchange data and ''allow for complete access, exchange, and use of'' certain health information. In other words, this definition does not require the transfer of massive quantities of data; it requires that such transfers be possible.

i. Other Comments

Comment: A commenter suggested that OIG continue to consider how data is being shared and ensure that information blocking is not occurring. The commenter specifically recommended that the safe harbor require that all VBE participants be able to review and have access to information on different EHR systems used in any value-based arrangement and have the ability to import and export data that can help further the purpose of the value-based arrangement. In addition, the commenter recommended that physicians and others providing care to beneficiaries under value-based arrangements should have the ability to select the EHRs that are best suited for the applicable patient population.

Response: The safe harbor does not mandate how or which types of EHR software or information technology services a donor or recipient may select. Because we are finalizing a change to eliminate the restriction on donations of equivalent technology, we hope that parties will have more flexibility to receive protected donations of EHR software that best suit the needs of the parties. However, we emphasize that this safe harbor is not specific to or limited to EHR software or information technology services donated in the context of value-based arrangements. The value-based safe harbors finalized here at paragraphs 1001.952(ee),(ff), and (gg) could be available to protect the donation of health information technology pursuant to a value-based arrangement, provided all conditions of an applicable safe harbor are squarely satisfied. In addition, for the reasons that we explain in detail above, we are not finalizing information blocking provisions as conditions of this safe harbor.

OIG remains committed to addressing information blocking through other authorities. Parties should submit information blocking complaints to HHS through the Report Information Blocking portal (*https://healthit.gov/report-info-blocking*).

Comment: A commenter asked OIG to clarify when certain arrangements such as data sharing arrangements could implicate the Federal anti-kickback statute. The commenter posited that when technology is shared for transitions of care or to streamline and improve the referral process as a matter of CMS policy, it does not implicate the Federal anti-kickback statute.

Response: A ''data sharing arrangement'' can vary greatly in the scope of data or services being exchanged. Simply transmitting individual patient data for transitions of care between, for example, an acute care provider and post-acute care provider would not implicate the statute. However, sharing specific patient data for care of that patient is distinct from a data sharing arrangement that involves aggregating data for research, marketing, or other purposes unrelated to treating the specific patients whose data is being shared. With respect to technology for data sharing, many types of ''technology'' would constitute remuneration under the Federal anti-kickback statute but, as we have repeatedly stated, certain limited-use technology that is integral to the services an individual or entity provides would not implicate the statute.[121] The parties to a particular data sharing arrangement would need to perform an analysis of the facts and circumstances to determine whether any data or technology shared constitutes remuneration under the statute and, if so, whether a safe harbor such as the EHR safe harbor could protect the donation. The advisory opinion process is also available for a legal opinion regarding the facts and circumstances of a particular arrangement.

[119] Section 4003(a)(2), Public Law 114–255, 130 Stat. 1033.

[120] *Id.*

[121] 78 FR at 79210 (''The donation of free access to an interface used only to transmit orders for the donor's services to the donor and to receive the results of those services from the donor would be integrally related to the donor's services. As such, the free access would have no independent value to the recipient apart from the services the donor provides and, therefore, would not implicate the anti-kickback statute.'').

10. Personal Services and Management Contracts and Outcomes-Based Payment Arrangements (42 CFR 1001.952(d))

Summary of OIG Proposed Rule: We proposed to modify the existing safe harbor for personal services and management contracts at paragraph 1001.952(d). For paragraph 1001.952(d)(1) we proposed to: (i) Substitute for the requirement that aggregate compensation under these agreements be set in advance a requirement that the methodology for determining compensation be set in advance; (ii) eliminate the requirement that if an agreement provides for the services of an agent on a periodic, sporadic, or part-time basis, the contract must specify the schedule, length, and the exact charge for such intervals; and (iii) change the paragraph numbering. These proposals are summarized at sections III.B.10.a and b below.

We also proposed to create new paragraphs 1001.952(d)(2) and (3) to protect certain outcomes-based payments (as defined). The proposals for this new protection are summarized at section III.B.10.c, d, and e below.

Summary of Final Rule: We are finalizing the modifications to the existing safe harbor for personal services arrangements at paragraph 1001.952(d)(1), as proposed. We are finalizing the new provisions for outcomes-based payments at paragraphs 1001.952(d)(2) and (3), with modifications summarized at sections III.B.10.c, d, and e below.

a. Elimination of Requirement To Set Aggregate Compensation in Advance

Summary of OIG Proposed Rule: We proposed to substitute for the requirement that aggregate compensation under these agreements be set in advance a requirement that the methodology for determining compensation be set in advance in paragraph 1001.952(d)(1).

Summary of Final Rule: We are finalizing this modification as proposed.

Comment: Commenters on this topic overwhelmingly supported the proposed removal of the requirement to set aggregate compensation in advance and its replacement with a requirement that the compensation methodology be set in advance. Commenters offered a variety of reasons for their support. For example, a commenter valued these changes because they provide enhanced flexibility to independent medical groups and other providers seeking to develop innovative care delivery models. Another commenter suggested that this change allows for greater flexibility in personal services arrangements while continuing to incorporate safeguards that limit potential abuse.

Another commenter explained a view that incentive compensation in comanagement arrangements or bundled payment arrangements often has to be structured in a formulaic manner, and it is not possible for hospitals and physicians to know at the beginning of the arrangement whether and to what extent the physicians may meet the requirements for earning incentive compensation or the actual amount of compensation available. The commenter believed the proposed change would address this existing impediment to safe harbor protection. The commenter also appreciated that the proposed change would more closely parallel the set-in-advance requirement under the physician self-referral law exception for personal services arrangements at 42 CFR 411.357(d), which would simplify a stakeholder's analysis of protection under the safe harbor and exception when both laws apply to an arrangement.

Response: We are finalizing this provision as proposed. This change modernizes the safe harbor and should provide enhanced flexibility to the health care industry to undertake innovative arrangements, including arrangements that support the transition to value and better coordinated care for patients.

Comment: A commenter expressed concern that certain proposed changes to this safe harbor were not specific enough. In particular, the commenter warned that replacing a requirement to set aggregate compensation in advance with a requirement to identify the methodology for determining compensation could allow entities to structure agreements that look acceptable on the surface, but actually take into account the volume and value of referrals.

Response: We agree with the commenter that implementing a more flexible approach to specifying compensation could protect arrangements that differ in structure from arrangements the safe harbor currently protects. However, we believe that other safe harbor conditions mitigate the risk identified by the commenter, namely the protection of arrangements that take into account the volume and value of referrals. For example, we continue to require parties seeking protection under the safe harbor to adhere to the safe harbor's other conditions (*e.g.,* aggregate compensation must be consistent with fair market value in an arm's length transaction and may not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties). Arrangements that do not squarely satisfy these conditions would not be protected by the safe harbor. In other words, despite the safe harbor's increased flexibility related to specifying compensation, the safe harbor would not protect an arrangement by which the aggregate compensation is determined in a manner that takes into account the volume or value of referrals or other business generated.

Comment: Some commenters requested further guidance on whether a payment methodology based on ''actual expenses incurred'' constitutes a methodology that is sufficiently set in advance to satisfy the safe harbor condition as proposed. For example, a commenter inquired about compensation in an arrangement wherein a hospital leases an employed clinician from a physician practice on a full- or part-time basis. Specifically, the commenter sought clarification regarding whether the safe harbor would protect compensation under the employee lease from the hospital to the practice based on a methodology related to the physicians practice's actual expenses incurred for employing such clinician (*e.g.,* salary, benefits, bonus, liability insurance, overhead). Another commenter requested guidance as to whether payment based on annual aggregate costs could be prorated to an hourly rate and charged based on completion of time records.

Response: We appreciate the commenter's examples of potential arrangements that may be structured to comply with the personal services safe harbor as finalized. It is possible to structure an arrangement to fit within the safe harbor by using an hourly rate or other set, verifiable formula provided that all other conditions of the safe harbor are met. However, whether compensation under an employee lease that is based on actual expenses incurred would satisfy the requirement that the compensation methodology be set in advance or otherwise meet the safe harbor would depend on the facts and circumstances. The commenter specifically cited salary, benefits, liability insurance, overhead expenses, and a bonus. For example, assume that the hospital leases the physician part-time from the physician's practice and agrees to pay the practice the percent of the practice's actual expenses in employing that physician that correlate to the percentage of the physician's work actually performed for the hospital. We would expect that an

employee's salary, benefits, and liability insurance typically would be set in advance; overhead expenses possibly also would be set in advance. Consequently, the parties could structure these elements of the part-time employee's expenses to satisfy the condition that the compensation methodology be set in advance. However, depending on the structure and criteria for receiving a ''bonus,'' that portion of the practice's expenses—and therefore, the compensation methodology for the part-time employee lease—might not be set in advance and might not meet other criteria of the safe harbor. For example, if a bonus that took into account the volume or value of referrals between the parties was part of the compensation under the lease, the hospital's compensation to the practice for the part-time employee lease would not be protected by the safe harbor.

The intent behind these modifications is to provide enhanced flexibility while mitigating the risk of parties periodically adjusting the agent's compensation to reward referrals or to promote unnecessary utilization of services. Parties seeking protection under this safe harbor must evaluate the specific facts and circumstances of their arrangement to determine whether the compensation methodology over the term of the agreement is set in advance before any payment under the arrangement is made. Any remuneration also must meet all other conditions of the safe harbor for protection.

Comment: Some commenters agreed with our proposals but asked OIG to define certain terminology under the safe harbor such as ''fair market value'' and ''does not take into account the volume or value of referrals,'' and asked OIG to harmonize OIG's interpretations of this terminology under the Federal anti-kickback statute with CMS's interpretations of this terminology under the physician self-referral law in the proposed rule CMS issued in connection with the Regulatory Sprint (CMS NPRM),[122] to the extent possible given the differences in the two laws. For example, a commenter recommended that OIG adopt CMS's interpretation of the volume or value standard as proposed by CMS in the CMS NPRM. Another commenter sought clarification from OIG that incentive compensation paid to a physician under a comanagement, bundled payment, or internal cost savings arrangement would not take into account the volume or value of referrals under the Federal anti-kickback statute if the physician is paid a percentage of savings per ''case.'' According to the commenter, the more cases performed may result in more savings, more losses, or something in between. A commenter asserted that ''value'' in the construct of ''fair market value'' should not solely relate to what an entity would pay regardless of the outcome. According to the commenter, OIG should consider defining ''fair market value'' in a manner that recognizes the value of savings attributable to the services to the entity paying the incentive compensation rather than the time value of the services or the value of the services based on metrics, or any relevant fee schedule. A commenter recognized that OIG cannot opine on ''fair market value'' in an advisory opinion but requested that OIG explain whether certain compensation methodologies (*e.g.,* using an hourly rate as a compensation methodology or a percentage of savings attributable to an agent) could constitute fair market value under the Federal anti-kickback statute.

Another commenter sought confirmation that OIG interprets the term ''commercially reasonable'' consistent with CMS's proposed interpretation in the CMS NPRM, specifically ''that the particular arrangement furthers a legitimate business purpose of the parties and is on similar conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.''

Response: We did not propose to define or interpret fair market value, commercially reasonable, or the phrase ''takes into account the volume or value of referrals or business otherwise generated,'' nor are we adopting the commenter's suggestion that we interpret these terms, for purposes of applying the Federal anti-kickback statute and safe harbor regulations, consistent with CMS's interpretations of such terms. These terms have long existed throughout our existing safe harbors at section 1001.952 without further definition or interpretation by OIG and are well-established. Whether or not fair market value is or was paid or received for any personal services provided by an agent to a principal under this safe harbor depends on the specific arrangement's facts and circumstances, and we decline to interpret examples with limited information.

Comment: Certain commenters were concerned that Indian health care service providers cannot utilize this safe harbor because of the requirement that each party in the arrangement pay fair market value for services. According to commenters, the fair market value for Indian health facility jobs and services may not align with the fair market value elsewhere. Some of these commenters recommended that the fair market value for Indian health facilities be lowered and relate more to the economic realities of provider recruitment and retention in tribal communities. Commenters also noted that some part-time contractors currently use the fair market value standard to extract pay that exceeds the fair market value for jobs within Indian health programs.

Response: We understand the commenters' concerns with respect to establishing personal services arrangements in facilities or regions where salaries might be lower than the fair market value found in other nearby areas. We are not defining fair market value or further specifying the appropriate methodologies for parties to use when determining fair market value in this final rule. Based on our law enforcement experience, arrangements in which parties offer or provide free or below fair market services to those in a position to refer federally payable business to the offeror can be problematic under the Federal anti-kickback statute. However, we agree that fair market value can vary by region, setting, or other factors. For example, an hourly rate for certain specialist services in Manhattan likely would be higher than the hourly rate for the same services in rural Mississippi or at an Indian health facility.

Comment: A commenter recommended that OIG expand the writing requirement within the safe harbor to include contemporaneous documentation rather than a signed agreement. The commenter noted that the CMS NPRM proposed to remove the formality of a signed agreement and modified this requirement in certain physician self-referral law exceptions to allow documentation that constitutes an agreement under applicable state law, which the commenter believes will ease the regulatory burden for stakeholders to document the arrangement.

Response: We did not propose to modify the requirement that an agency agreement be set out in writing, thus we are not finalizing any change to that requirement. As we explained above, the physician self-referral law and the Federal anti-kickback statute are different laws with different standards for liability. Having a signed, written agreement that meets all requirements of the safe harbor is a core safeguard that is necessary for parties to demonstrate that they intend to comply with all requirements of the safe harbor, have structured the compensation

[122] 84 FR 55766 (Oct. 17, 2019).

methodology appropriately, and have a meeting of the minds on the services and payment to be provided under the arrangement. However, we note that the safe harbor does not specify a particular format for the agreement. The written agreement requirement can be met either through a single, formal, signed agreement or through a collection of documents if such collection of documents includes all of the required elements of the safe harbor and is signed by the parties (*e.g.,* by signing each document that makes up the agreement, or by signing a single signed document that incorporates separate documents by reference).

b. Elimination of Requirement To Specify Schedule of Part-Time Arrangements

Summary of OIG Proposed Rule: We proposed to eliminate the condition in the safe harbor paragraph 1001.952(d)(5) that requires that if an agreement provides for the services of an agent on a periodic, sporadic or part-time basis, the contract must specify the schedule, length, and the exact charge for such intervals.

Summary of Final Rule: We are finalizing this modification as proposed.

Comment: Commenters generally appreciated the proposed removal of the requirement that, for part-time arrangements, the contract must specify the schedule, length, and the exact charge for such intervals. Multiple commenters stated that eliminating the requirement that part-time contractual arrangements specify exact interval schedules allows for greater flexibility in protected personal services arrangements, while the safe harbor continues to incorporate safeguards that limit potential abuse. For example, a commenter noted the proposal could apply to dialysis facility medical directors who provide their services on a part-time basis. The commenter highlighted the unpredictable nature of dialysis care and that the frequent need to respond to urgent medical emergencies can impede the ability of nephrologists serving as dialysis facility medical directors to adhere to predetermined schedules. In contrast, a commenter expressed concern that eliminating this requirement may increase the risk that either services will not be rendered or that the payment for services may vary based on referrals and recommended additional documentation requirements.

Response: We are finalizing the removal of the requirement to specify the exact schedule of part-time arrangements, as proposed. We note that this change to the safe harbor should accommodate a broad range of part-time or sporadic-need value-based payment and care arrangements in furtherance of the Department's goals in connection with the Regulatory Sprint. We did not propose additional documentation requirements, and we continue to believe, as we stated in the OIG Proposed Rule, that other conditions sufficiently safeguard against the harms mentioned by a commenter.[123]

c. Proposal To Protect Outcomes-Based Payments

Summary of OIG Proposed Rule: At proposed paragraphs 1001.952(d)(2) and (3), we proposed to protect outcomes-based payment arrangements between a principal and an agent that reward improving patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings, or by achieving one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care. We proposed several safeguards. Under proposed paragraphs 1001.952(d)(2), protected payments would be between parties collaborating to measurably improve or maintain improvement in quality of care or appropriately and materially reduce costs of payments (without diminution of the quality of care), and the agent receiving the payment would need to meet at least one evidence-based, valid outcomes measure meeting specified criteria, including selection based on credible medical support. Under proposed paragraph 1001.952(d)(2)(iii), the payment methodology would be set in advance, commercially reasonable, consistent with fair market value, and not determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties.

Additionally, at paragraph 1001.952(d)(2), we proposed safeguards to protect clinical decision-making, guard against stinting on care, and ensure written documentation, monitoring, periodic rebasing of outcome measures, and corrective action of deficiencies in the quality of care. The term of protected arrangements would be at least 1 year. At proposed paragraph 1001.952(d)(3), we proposed making certain entities ineligible for safe harbor protection under the outcomes-based payments provisions in a manner similar to the proposed definition of VBE participant at proposed paragraph 1001.952(ee)(12), and we proposed that outcomes-based payments would exclude payments related solely to achievement of internal cost savings for the principal. We indicated that we were considering excluding payments based on patient satisfaction or convenience measures.

Summary of Final Rule: We are finalizing, with modifications, the new protection for outcomes-based payments at paragraphs 1001.952(d)(2) and (3). We revised the definition of ''outcomes-based payment'' in paragraph 1001.952(d)(3)(ii) to clarify that the payment may be a reward for successfully achieving an outcome measure or a recoupment or reduction in payment for failure to achieve an outcome measure. Paragraph 1001.952(d)(2)(i) consolidates and streamlines proposed paragraphs 1001.952(d)(2)(i) and (ii) related to acceptable outcomes measures; to receive a protected outcomes-based payment, the agent must achieve one or more legitimate outcome measure selected based on clinical evidence or credible medical support and with specified benchmarks related to quality of care, a reduction in costs, or both. At paragraph 1001.952(d)(2)(vii)(B), we revised our proposal related to ''rebasing'' of outcomes measures to clarify that the parties must periodically (i) assess and (ii) revise benchmarks and remuneration under the agreement as necessary to ensure that any remuneration is consistent with fair market value in an arm's-length transaction as required by paragraph 1001.952(d)(2)(ii).

We finalize the proposed requirements related to fair market value, commercial reasonableness, and the volume or value of business at paragraph 1001.952(d)(2)(ii). At paragraph 1001.952(d)(2)(iii), we finalize the writing requirement proposed at paragraph 1001.952(d)(2)(viii). In paragraph 1001.952(d)(2), we finalize additional safeguards related to clinical decision-making, stinting on care, a 1-year term, monitoring, and counseling and promotion of unlawful business, as proposed.

At paragraph 1001.952(d)(3)(iii), we finalized the scope of entities ineligible for safe harbor protection for making outcomes-based payments to include: (i) Pharmaceutical companies; (ii) PBMs; (iii) laboratory companies; (iv) pharmacies that primarily compound drugs or primarily dispense compounded drugs; (v) manufacturers of a device or medical supply, as defined in paragraph (ee)(14)(iv); (vi) medical device distributors or wholesalers that are not otherwise manufacturers of a device or medical

[123] 84 FR 55744–45 (Oct. 17, 2019).

supply, as defined in paragraph (ee)(14)(iv) of this section; or (vii) DMEPOS companies. In the same paragraph, we finalize our policy to exclude payments for internal cost savings or payments based solely on patient satisfaction or patient convenience measures.

We clarify in both paragraph 1001.952(d)(2)(ii) and paragraph 1001.952(d)(3)(ii) that the remuneration may be ''between or among'' the parties, rather than being limited to remuneration from the principal to the agent. We reordered the provisions from paragraphs (d)(2)(iii)–(vii) without making additional substantive changes. We made technical corrections in paragraph 1001.952(d)(2) to replace the word ''satisfy'' with the word ''achieve'' in order to use a consistent term throughout the safe harbor.

Comment: Many commenters supported OIG's proposal to expand the existing safe harbor for personal services and management contracts by creating new provisions at paragraphs 42 CFR 1001.952(d)(2)–(3) to protect certain outcomes-based payments. Some expressed support for protection for outcomes-based payments but encouraged OIG to provide greater specificity regarding the types of payment arrangements, specific outcome measures, and specific requirements for measuring achievement of outcomes that would qualify for protection under these proposed provisions to the safe harbor. A commenter asked OIG to clarify that the list of examples in the OIG Proposed Rule's preamble was not all-inclusive, but merely a representative list of the types of arrangements that may be protected under the safe harbor. Another commenter cautioned against referencing or creating an exhaustive list of specific types of payments that could qualify as ''outcomes-based payments'' because that approach would be too limiting. Another commenter requested that OIG reiterate its recognition that outcomes-based payment arrangements may vary in structure and that the safe harbor should provide flexibility for arrangements designed to achieve appropriate quality of patient care as well as appropriate efficiency and cost-saving goals. Many commenters believed the proposals were unnecessarily limited, overly complex, and potentially difficult for physicians to implement, and another commenter found the monitoring of arrangements overly burdensome.

Response: We intend for the outcomes-based payments safe harbor to support outcomes-based payments that facilitate care coordination, encourage provider engagement across care settings, and advance the transition to value. At the outset, we note that in response to general comments regarding the complexity of this safe harbor and for the sake of clarity, we streamlined the language we had proposed in paragraphs 1001.952(d)(2)(i) and (ii) such that the safe harbor still expressly specifies that the agent must achieve one or more legitimate outcome measures selected based on clinical evidence or credible medical support, but we are not finalizing the proposed language relating to the measures being specific, evidence-based, and valid. As we explain in greater detail in section III.B.3.b above in our discussion of outcome measures in the care coordination safe harbor, based on public comment, we changed the terms ''evidence-based'' and ''valid'' to ''clinical evidence'' and ''legitimate'' to offer some additional flexibility while reflecting our intention that measures be credible and appropriate. In selecting outcome measures, parties have broad latitude under this safe harbor to identify opportunities for improving or maintaining the improvement of patient care and reducing costs to payors in ways that are scientifically valid, measurable, and transparent.

We are not limiting protection under the safe harbor to a specific set of arrangements such as value-based arrangements. In the OIG Proposed Rule, we listed certain arrangements that may be protected under the safe harbor, provided the arrangement meets every requirement of the safe harbor.[124] We are not limiting the protection provided by this safe harbor to a particular list of arrangements or particular types or structures of arrangements or measures.

We take a broader approach by providing additional protection to a variety of stakeholders, which should facilitate innovation in designing compensation arrangements that are value-based. As we stated in the OIG Proposed Rule, we strive to provide flexibility in this safe harbor, but we also must include appropriate safeguards, such as monitoring and assessment requirements, to protect patients and Federal health care programs.

Comment: We received comments on our proposed definition of ''outcomes-based payment'' and its interaction with other requirements. For example, a commenter recommended that we remove the language in the ''outcomes-based payment'' definition that appears to make effectively and efficiently coordinating care across care settings a required factor in an outcome measure. A commenter also asked that we harmonize the terms we use to describe ''outcome measures'' throughout the safe harbor. For example, a commenter indicated that the definition of ''outcomes-based payment'' is not consistent with the way payments are made under existing alternative payment models. A commenter recommended a technical change to paragraph 1001.952(d)(2) to specify that the safe harbor protects outcomes-based payments made by a principal to an agent as compensation for the services of the agent.

Response: We are not making the change to paragraph 1001.952(d)(2) suggested by a commenter to refer to payments from a principal to an agent. However, we note that the safe harbor protects any ''outcomes-based payment,'' and that term is defined in paragraph 1001.952(d)(3). In this final rule, we revised that definition to protect payments ''between or among a principal and an agent'' that meet certain criteria, as described in more detail below.

In addition, we removed the language in the definition of ''outcomes-based payment'' regarding effectively and efficiently coordinating care across care settings, and instead rely on a reference to paragraph 1001.952(d)(2)(i) in which outcome measures are described. We believe that this change also addresses the commenter's concern about different terminology in those two sections. We also are revising the proposed requirement that the outcome measure measurably improves quality of patient care or appropriately and materially reduces payor costs to provide that the measure must be used to quantify: (i) Quality improvements (or maintenance of improvements in quality); (ii) material reductions in payor costs or expenditure growth while maintaining or improving the quality of care for patients; or (iii) both. Finally, we note that this safe harbor is not the only option for protecting payments under alternative payment models. Participants in such models may be able to look to the safe harbor for CMS-sponsored models at paragraph 1001.952(ii), or the value-based safe harbors at paragraphs 1001.952(ee)–(gg).

Comment: A commenter urged OIG to use ''outcome measures'' under paragraph 1001.952(d)(2) consistently with the use of the term under paragraph 1001.952(ee) to reduce complexity.

Response: We interpret the term ''outcome measure'' under this safe harbor to have the same meaning as

[124] 84 FR 55745 (Oct. 17, 2019).

under any other safe harbor that uses it, including paragraph 1001.952(ee). We note, however, that different safe harbors protect different types of remuneration, include different safeguards, and use additional terms. For example, in the safe harbor for care coordination arrangements, the ''outcome or process measure'' must have a benchmark related to improving or maintaining improvements in the coordination and management of care for the target patient population, while ''outcome measures'' under this safe harbor must have benchmarks that relate to improving or maintaining the quality of patient care, reducing costs or growth in expenditures to payors, or both. If a party seeks safe harbor protection for a particular arrangement, the arrangement need only meet one safe harbor to qualify for protection but the arrangement must comply with all conditions of the chosen safe harbor.

Comment: A commenter urged that outcomes-based payments should include a service component to prevent sham arrangements that simply maintain the status quo. Similarly, a few commenters suggested that OIG limit parties that may pay outcomes-based payments to parties participating within a VBE to prevent fraud and abuse, such as sham arrangements through which no service is provided. A commenter asked whether an outcomes-based payment agreement that requires exclusive or minimum level of use of a product (*e.g.,* product standardization) to achieve an outcomes-based payment could be protected by the safe harbor as long as the principal makes a determination that such the requirement for exclusivity or minimum use will not preclude it from making decisions in its patients' best interests.

Response: As we stated in the OIG Proposed Rule, measures that simply seek to reward the status quo would not meet the safe harbor condition that requires parties to select legitimate outcome measures.[125] However, we are not limiting the scope of entities that may make outcomes-based payments to VBEs or VBE participants. We believe that the conditions parties must meet for safe harbor protection will sufficiently mitigate the risk of fraud and abuse.

We agree that the safe harbor does not necessarily preclude product standardization. If the product standardization measures selected by the parties under the outcomes-based payment arrangement do not limit any party's ability to make decisions in their patients' best interest and meet the other terms of the safe harbor, then they could be part of an outcomes-based payment arrangement.

Comment: A trade association commented that only sophisticated health systems with advanced data analytics have the capability to internally develop outcome measures while small, underserved, and rural practices would not have the resources to develop these measures internally. For example, a commenter noted that measuring outcomes can be a challenging and resource-intensive process that takes time to evaluate, especially on the individual participant level in a large entity with significant numbers of participants and multiple specialty areas.

Response: We recognize that structuring and implementing outcomes-based payment arrangements that satisfy the conditions of this safe harbor may be more onerous than structuring and implementing traditional personal service arrangements under the existing personal services and management contracts safe harbor (*e.g.,* a party striving to satisfy the outcomes-based payment arrangements provisions must determine legitimate outcome measures, establish the types of services to be performed to achieve an outcome measure, set benchmarks, monitor and assess achievement, and ultimately achieve outcome measures). We understand the commenter's concern regarding the potential administrative and financial impact that developing outcome measures may have on small, underserved, and rural providers. Participation in an outcomes-based payment arrangement is entirely voluntary, as is structuring outcomes-based payments to satisfy the conditions of this safe harbor. To the extent that parties wish to enter into an outcomes-based payment arrangement and structure such arrangement to satisfy the conditions of this safe harbor, the parties have discretion in the selection of outcome measures. Providers serving small, underserved, or rural communities may select outcome measures that would not impose an inappropriate financial burden on the parties to effectuate.

Comment: A commenter asked OIG to include process measures (*e.g.,* providing or not providing a specific treatment) that are supported by strong evidence of improving an outcome within the types of valid outcome measures that may serve as the basis for payment under the safe harbor. Another commenter recommended that we require outcomes-based arrangements to include a service component.

Response: We agree that process measures supported by strong evidence of improving an outcome may serve as a component of outcome measures that an agent must achieve to receive an outcomes-based payment. For example, an outcomes-based payment arrangement may measure the agent's compliance with certain steps of a care process (*e.g.,* providing mammograms) to improve a specific health outcome. In section III.B.3.b above, we explain the rationale for permitting process measures to be included in the care coordination arrangements safe harbor but not in the outcomes-based payment provisions discussed here (although a process measure could be included as part of an outcomes measure); that rationale focuses on the different remuneration permitted under the two safe harbors and the different standards set forth by each safe harbor.

Under the modified regulatory text, outcome measures must be selected based on clinical evidence or credible medical support and be used to: (i) Quantify improvements or maintenance of improvements in the quality of patient care; (ii) quantify a material reduction in costs to, or growth in expenditures of, payors while maintaining or improving quality of care for patients; or (iii) both. In addition, as we proposed in the OIG Proposed Rule a ''measure'' related to patient satisfaction or convenience would not meet the criteria of an outcome measure.[126] For similar reasons to those we discuss in connection with outcomes measures for paragraph 1001.952(ee), the final rule at paragraph 1001.952(d)(3)(iii)(C) provides that an outcomes-based payment based *solely* on patient satisfaction or patient convenience measures would not be protected. We recognize that patient satisfaction and patient convenience can be relevant factors in patient care. However, we do not consider these types of measures, standing alone, to provide adequate protection against abusive or sham payment arrangements for purposes of granting safe harbor protection.

We anticipate that most outcomes-based arrangements would include certain services to meet the conditions of the safe harbor, and the regulatory text includes several references to services. However, we believe that adding a separate requirement specific to performing services could add confusion, and that existing conditions in paragraph 1001.952(d)(2) safeguard against sham arrangements.

[125] 84 FR 55746 (Oct. 17, 2019).

[126] 84 FR 55708 (Oct. 17, 2019).

Comment: A commenter asked OIG not to require outcome measures to measurably improve the quality of patient care once the quality of care metric has been achieved. Instead, the commenter suggested that OIG focus on payment incentives that reduce costs after quality targets are met. On the other hand, a commenter expressed concern that allowing payment for ''maintaining improvement'' would invite sham arrangements that disguise payments in exchange for referrals for merely maintaining the status quo.

Response: We share the concern about the potential for sham arrangements associated with maintaining cost or quality. However, we also recognize that parties may succeed in reaching the desired outcome on quality or cost containment but need to be incentivized to maintain it to prevent subsequent reductions in attained quality or cost containment. To achieve the desired outcome, parties may need to invest resources at the beginning of an arrangement (*e.g.,* to develop new protocols and engage in training). However, a continued expenditure of resources also may be necessary to avoid regression from any progress made. These are the types of issues we would expect parties to assess and, as necessary, revise benchmarks and remuneration under the arrangement to benchmarks to continue to achieve the desired outcome on a periodic basis. For example, if parties had an outcome measure related to reducing falls to a certain level from a starting benchmark point in a skilled nursing facility, and they eventually achieve a fall rate benchmark that no longer has room for improvement, a revised outcome measure might be to maintain that low fall rate (*i.e.,* the new fall rate becomes the starting benchmark, and the outcome measure is to maintain it rather than reduce it). Any outcomes-based payment made for a new outcome measure would still have to meet all conditions of the safe harbor, including that the methodology for setting compensation is consistent with fair market value. For example, the fair market value of an outcomes-based payment made to an agent to maintain the desired level of quality of care may be lower than the fair market value of an initial outcomes-based payment made for implementing operational changes necessary to achieve the quality of care outcome measure.

Comment: A commenter indicated that it currently operates outcomes-based payment arrangements and suggested that OIG impose the following three requirements to ensure that all outcomes-based payments are legitimately made toward advancing the clinical and cost-saving goals of the arrangement and not merely payments for referrals: (i) Require outcome measures to be well-defined, meaningful to patients, achievable in a defined timeframe, and agreed upon by the parties; (ii) require outcome measures to be tracked through claims data, existing registries, EHRs, or other low-cost mechanisms; and (iii) require the arrangement to deliver measurable outcomes that improve patient quality of care and other benefits to the health care system through lower cost of care, other efficiencies, or shared accountability, or both.

Response: We appreciate the commenter's helpful suggestions. While we are not using the precise wording offered by the commenter, we believe the language finalized in the regulation captures many of the concepts suggested by the commenter. Similar to the commenter's suggestion of requiring meaningful, well-defined outcome measures, we require that the outcome measures be selected based on clinical evidence or other credible medical support and be used to quantify improvements to or maintenance of improvements in the quality of care or material reductions in cost to (or growth in expenditures of) payors, while maintaining or improving the quality of care of patients. We are not setting a timeline by which parties must achieve outcomes or requiring that parties must specify a timeline under which outcomes must be achieved because we recognize that the timeframe necessary to achieve certain outcome measures can vary greatly, depending on the measure and other characteristics, and that it may be challenging for parties to specify a certain timeline to achieve outcomes. Likewise, we do not specify any particular mechanism for tracking progress toward meeting outcome measures. We are not requiring parties to track outcome measures through claims data. However, the parties must regularly monitor and assess the agent's performance under the specified outcome measure(s), including its impact on patient quality of care and make any necessary adjustments. Parties also must periodically assess and, as necessary, revise the benchmarks and remuneration under the arrangement to ensure remuneration is consistent with fair market value. We do not believe mandating specific documentation methods is a necessary safeguard against fraud and abuse; parties may conduct and document such monitoring in any way that makes sense for the particular arrangement.

Comment: A commenter asked OIG to remove the proposed requirement that an outcome measure ''appropriately and materially'' reduce costs or growth in expenditures for payors because the commenter believed this provision was too subjective. A commenter requested that OIG provide greater certainty to stakeholders by establishing concrete methods that parties could use to determine whether an outcome measure improves quality of care under an arrangement. Another commenter disagreed with the proposed safe harbor requirement that the agent achieve the outcome measure in order to receive payment, asserting that constant achievement of any outcome measure is not practical in health care.

Response: We are making certain changes to ensure that parties appropriately measure and quantify the results of the arrangement on patient quality of care and costs. We are finalizing our proposal requiring the agent to achieve the outcome measure for the payment to be protected.[127] We believe this requirement serves as an important safeguard to ensure that remuneration is for legitimate outcomes anticipated through implementing the arrangement and is not a vehicle for rewarding referrals. We are not requiring particular methods to evaluate quality improvements (or maintenance of improvements in quality) under any protected arrangement because we believe that evaluation methods may be specific to each arrangement and may evolve in the future as parties innovate in new ways. We are modifying the proposed language by replacing ''appropriately and materially'' with a requirement that the agent achieve one or more legitimate outcome measures that meet conditions described elsewhere in this preamble. We believe this modification will allow parties additional flexibility to determine how to quantify quality improvements (or maintenance of improvements in quality) to accommodate different types of outcomes-based payment arrangements among a variety of stakeholders.

[127] We recognize that the Federal anti-kickback statute applies both to the offer and the receipt of remuneration, and parties may not know at the time of the offer of an outcomes-based payment (*i.e.,* when the parties develop and initiate the arrangement) whether the outcome measure(s) will be achieved. Assuming all other safe harbor conditions are met when the remuneration is offered under an outcomes-based payment arrangement, the offer would be protected, even if the agent fails to achieve the outcome measure. However, any payment made for an outcome measure not successfully achieved would not meet the safe harbor conditions under paragraph 1001.952(d)(i) and would not be protected.

Comment: Numerous commenters urged OIG to broaden its proposal to protect payments that solely provide cost savings to a payor to include cost savings to providers. Some commenters argued that limiting protection to arrangements that achieve cost savings to a payor would make the safe harbor unworkable in practice and encouraged OIG to include arrangements that achieve cost savings to a provider to incentivize changes in physician behavior that are necessary to facilitate the transition to value-based care. A commenter posited that outcomes-based payments by nature involve standardization on a given system, protocol, or both to improve efficiencies and better coordinate and deliver care.

A few commenters indicated that cost savings arrangements for cost-reporting providers would not immediately produce cost reductions for payors but may eventually lower Medicare costs because the cost reductions may be reflected in future bundled payment rates.

Response: Having considered the comments, we decline to broaden the safe harbor to protect outcomes-based payments for arrangements that reduce internal costs only to the providers making the payments. We are concerned that such payments, while potentially beneficial in generating efficiencies, pose risks to patient care that outweigh the potential for the arrangements to further the care coordination and efficiency goals of this rulemaking if protected.

In some cases, such as hospital-physician gainsharing, arrangements that reduce internal costs may benefit only the hospital making the payments without necessarily contributing to better care coordination, improvements in quality of care, or appropriate reductions in costs. We are concerned that some payments, such as a payment to select a less expensive device or to discharge a patient more quickly, could lead to reductions in the quality or safety of patient care. Moreover, apart from quality of care concerns such payments would not offer a corresponding reduction in the payments made by Medicare or another Federal health care program. In the absence of a potential efficiency benefit to Federal health care programs, and in light of patient care concerns, we are not protecting payments that relate solely to the achievement of internal cost savings for the principal making the payment as an ''outcomes-based payment.''

However, properly structured arrangements that compensate physicians for services performed and achieve hospital internal cost savings can serve legitimate business and medical purposes. Depending on the specific facts and circumstances, such arrangements could potentially be structured in a manner that complies with paragraph 1001.952(d)(1), as finalized.

Comment: Numerous commenters opposed the proposed safe harbor requirement that the methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of an agreement be consistent with fair market value, commercially reasonable, and not be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties, arguing that there are no industry standards applicable to outcomes-based payments available to date. A commenter expressed concern about only prohibiting the aggregate compensation from being determined in a way that ''directly'' takes into account the volume or value of referrals. Others supported these safe harbor requirements but asked for clarification from OIG on these terms, or asked OIG to align OIG's view of these standards to be consistent with the definitions of these terms proposed in the CMS NPRM as they relate to the physician self-referral law.

Others argued that legitimate, outcomes-based arrangements should be able to take into account the volume or value of referrals within the payment methodology. A few commenters suggested that OIG remove the fair market value requirement.

Response: We recognize that the process of evaluating whether an outcomes-based payment arrangement is consistent with fair market value may evolve and adapt as the health care industry shifts to value-based care payment models and outcomes-based payments. However, we believe that ensuring that the aggregate remuneration is consistent with fair market value helps ensure that monetary remuneration is paid for services that achieve legitimate outcome measures rather than referrals.

We are not adopting any particular standard for determining that the aggregate compensation methodology is consistent with fair market value to provide parties sufficient flexibility to analyze fair market value as applicable to specific arrangements and in arrangements that may not currently exist today. As explained above in our discussion of the elimination of the requirement to set aggregate compensation in advance, we decline to adopt the fair market value standard proposed by CMS under the physician self-referral law. We are finalizing our proposal to require that the compensation methodology for determining the outcomes-based payment not directly take into account the volume or value of referrals or other business generated between the parties. We believe this will provide parties flexibility to structure arrangements that incentivize providers to achieve an outcome measure, even if the methodology indirectly takes into account the volume or value of referrals.

Comment: A commenter questioned whether the safe harbor protects ''reverse-flow payments'' from an agent to a principal and recommended that OIG revise the definition for ''outcomes-based payment'' to protect payments from an agent to a principal when a targeted outcome or cost metric has not been achieved (*i.e.,* shared-losses payments).

Response: In the OIG Proposed Rule, we explained that a shared-losses payment could constitute an ''outcomes-based payment.'' [128] We are finalizing this position through revisions to the regulatory text at paragraph 1001.952(d)(3)(ii) to clarify that an outcomes-based payment is a payment ''between or among a principal and an agent'' that meets the criteria listed in paragraphs 1001.952(d)(3)(ii)(A) and (B), and includes payments in the form of recoupment from or reduction in payment to an agent.

Comment: Several commenters objected to the safe harbor including a specific timeframe after which parties seeking protection for outcomes-based payments would have to rebase their benchmarks. Commenters noted that any such time limits would be artificial. A commenter concerned with the negative effects of annual rebasing on preventive care provided the following example: One clinician takes preventive care steps to prevent colon cancer or to identify cancer at an earlier stage (*e.g.,* through colonoscopies, blood work) in the first year, which has the effect of reducing the risk of cancer for 5 years, while another clinician does not take any preventive care steps for a patient and the patient develops cancer 4 years later. According to the commenter, if rebasing is done on an annual basis, the second clinician would be rewarded for providing care at no cost and good outcomes during that 1 year, while the first clinician would not be rewarded because the clinician provided high-cost care with no discernible improvement of outcomes during that limited timeframe.

[128] 84 FR 55745 (Oct. 17, 2019).

Some commenters noted that finalizing a safe harbor condition that specifies timeframes for rebasing may have a negative impact on participation in outcomes-based arrangements. For example, because margins for improvement against benchmarks may be more challenging or impossible to meet over time, parties may be disincentivized to enter into these arrangements in the first place, or incentivized to unwind them after initial improvements, due to concerns about having an arrangement structure that does not squarely meet a safe harbor. Some of the commenters noted that, if there must be a specific timeframe in the safe harbor, that timeframe should be at least 5 to 10 years. In contrast, a commenter recommended that benchmarks be adjusted at least yearly to limit the risk that ''evergreen'' arrangements could be used as a vehicle to evade legitimate outcome obligations and instead to reward referrals.

Several commenters supported the standard we proposed in the OIG Proposed Rule requiring outcome measures to be periodically rebased, as applicable, during the term of the agreement. As an alternative, a commenter suggested that OIG revise this provision to require that the parties periodically reevaluate whether an outcome measure should be rebased throughout the term or expressly state that under some circumstances it may be appropriate upon review to maintain an existing outcome-based measure. In support of a nonspecific periodic review approach, commenters noted that the time period for implementing interventions and other actions needed to influence outcome measures can vary greatly, as can the time period needed for results to fully appear in outcome measures data. In addition, commenters asserted that some outcomes measures may not be tied to a baseline performance level at all. Commenters also highlighted that outcomes-based payments may be made for maintaining improvement in quality of patient care, in which case the targets for the outcomes-based payment would not be altered. A commenter noted that providers and collaborators continually analyze their results, and value-based purchasing programs incentivize parties to adjust outcome measures in a timely manner. We also received a request for clarification on any durational limits on outcome-based payments or if there are parameters related to when they must end (*i.e.,* whether an arrangement must end upon achieving the initial outcome measure or if it can continue through implementing a new outcome measure or maintaining the initial achievement).

Response: We note first that for an agent to receive a protected outcomes-based payment under the final safe harbor, the agent must have achieved a specified, legitimate outcome measure. For an outcome to be measurable, there must be some sort of benchmark, whether that benchmark is a starting point (*e.g.,* a 10 percent reduction from X) or reflects an end point (*e.g.,* 90 percent of the time, X happened or was avoided). We agree with commenters that a one-size-fits-all approach is not appropriate for assessing benchmarks. However, we also agree with the commenter who highlighted the concern we raised in the OIG Proposed Rule about ''evergreen'' arrangements [129] in which outcome measures are not properly monitored and the remuneration is paid in exchange for referrals, after any intended benchmarks have been met (or without determining that the outcome measure was achieved).

To illustrate, we point to the example from a commenter as it is summarized above, with two clinicians taking different approaches to patients with respect to colon cancer prevention and detection. Setting aside the potentially disparate impact on patient health, health outcomes, and quality of care, and looking only at costs for purposes of this example, one clinician may increase costs to payors in the short term by increasing preventive care but may save money in the longer term, while the other clinician may have limited costs in the short term, but by failing to detect the cancer early may increase costs to payors in the long term. However, it is not clear in the example what the outcome measure might be. By way of example for illustrative purposes, the U.S. Preventive Services Task Force recommends colon cancer screening beginning at age 50. A reasonable outcome measure might be a specific percentage increase in the practice's patient population first getting screened between age 50 and 55. Parties would need to evaluate an appropriate benchmark year (*i.e.,* a percentage increase in first screenings from which year), and whether over time the percentage change should be updated, the benchmark year should be changed, or both. In addition, the amount of remuneration paid for achieving the outcome measure should be reassessed to determine whether it is fair market value. For example, a practice may need to develop new processes, training, and take other steps initially to achieve an outcome measure. While certain work must continue in future years to continue achieving the desired outcomes (whether it is for continuing to improve quality of patient care or materially reduce cost, or to maintain the achieved improvements in those areas), the outcomes-based payment may be less than it was during the initial year(s). If the outcome measure was based on the cost savings over the course of a year, an annual reassessment of the benchmark and remuneration would be appropriate to meet that safe harbor requirement. We also recognize that some outcome measures might be on a longer timetable for reassessment (*e.g.,* a percentage reduction in costs over a 5-year time span). Therefore, the outcome measure might not need to be reassessed for 5 years (but an outcomes-based payment also would not be protected by this safe harbor until such outcome is achieved).

We have revised the regulatory text in the final rule to address many of the issues the commenters raised. These revisions are consistent with the substance of what we proposed in the OIG Proposed Rule. In the OIG Proposed Rule, we had solicited comments on defining the term ''rebasing'' and had described the fraud and abuse risk we were trying to prevent (*e.g.,* arrangements in which outcome measures are not properly monitored or assessed and could be used as a vehicle to reward referrals well after the desired provider behavior change or savings benchmark has been met [130]). Specifically, in this final rule, rather than stating that, for each outcome measure, the parties must ''rebase during the term of the agreement, to the extent applicable,'' we are stating that the parties must ''[p]eriodically assess and, as necessary, revise benchmarks and remuneration under the agreement to ensure that the remuneration is consistent with fair market value in an arm's-length transaction as required by (d)(2)(ii).'' Thus, for safe harbor protection, all parties must assess the arrangement periodically (*e.g.,* determine whether continued use of a benchmark or a measure is appropriate and whether the remuneration is appropriate for achieving that outcome measure), and then the parties should make any adjustments to benchmarks or remuneration that may be necessary to meet other conditions of the safe harbor.

[129] 84 FR 55747 (Oct. 17, 2019).

[130] 84 FR 55747 (Oct. 17, 2019).

d. Outcomes-Based Payments: Entities Not Eligible for Protection

Summary of the OIG Proposed Rule: We proposed making certain entities ineligible for safe harbor protection under the outcomes-based payments provisions, as described in section III.B.10.c.

Summary of the Final Rule: We are finalizing our policy to make certain entities ineligible for safe harbor protection. Specifically, the following entities will be ineligible to use the safe harbor: (i) Pharmaceutical companies; (ii) PBMs; (iii) laboratory companies; (iv) pharmacies that primarily compound drugs or primarily dispense compounded drugs; (v) manufacturers of a device or medical supply, as defined in paragraph (ee)(14)(iv); (vi) medical device distributors or wholesalers that are not otherwise manufacturers of a device or medical supply, as defined in paragraph (ee)(14)(iv) of this section; and (vii) DMEPOS companies. In addition, the final rule clarifies that DMEPOS companies do not include a pharmacy or a physician, provider, or other entity that primarily furnishes services.

Comment: Numerous commenters, including stakeholders representing pharmaceutical and medical device manufacturers and laboratories, opposed carving out pharmaceutical and medical device manufacturers, manufacturers, distributors, and suppliers of DMEPOS, and laboratories from the protection under the safe harbor. For example, a commenter suggested that medical device manufacturers should be protected because they can make valuable contributions to value-based care. Other commenters supported OIG's proposal, with some commenters requesting that we make additional entities ineligible for protection, such as device manufacturers, distributors, wholesalers, PBMs, and pharmacies.

Response: As laid out in the OIG Proposed Rule, we remain concerned that pharmaceutical and medical device companies, DMEPOS companies, and laboratories may inappropriately use outcomes-based payment arrangements to market their products or divert patients from a more clinically appropriate item or service, provider, or supplier without regard to the best interests of the patient or to induce medically unnecessary demand for items and services.[131] In the OIG Proposed Rule, we proposed to exclude from safe harbor protection payments made directly or indirectly by a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies, or a laboratory. We proposed to exclude these parties based on our enforcement and oversight experience and for reasons similar to the reasons for proposed exclusion of these entities from the definition of VBE participant (for further discussion of these reasons, readers are referred to section III.B.2.e.ii above). We explained that this provision reflected our concerns that these types of entities are heavily dependent on prescriptions and referrals and might use outcomes-based payments primarily to market their products to providers and patients. We further said we were considering excluding pharmacies (including compounding pharmacies), PBMs, wholesalers, and distributors for the same reasons we proposed to exclude them from the definition of VBE participant. With respect to PBMs, wholesalers, and distributors, their businesses are closely connected to the sale of manufacturer products, which provides an additional reason to exclude them along with manufacturers.

Additionally, we said in the OIG Proposed Rule that we were considering for the final rule the exclusion of medical device manufacturers from participation in the outcomes-based payments arrangements safe harbor.[132] We explained our historical law enforcement experience with matters involving kickbacks paid to physicians, hospitals, and ambulatory surgical centers to market various medical devices, such as devices used for invasive procedures; in some cases, these schemes resulted in patients getting medically unnecessary care. We also explained our longstanding concern with physician-owned distributorships of medical devices because of financial incentives to perform more (or more extensive) procedures than are medically necessary and to use the devices sold by the distributorship instead of more clinically appropriate devices.[133]

For the reasons stated in the OIG Proposed Rule, we are finalizing the provision as follows: Outcomes-based payments made directly or indirectly by the following entities are ineligible for protection under this safe harbor: (i) A pharmaceutical manufacturer, distributor, or wholesaler; (ii) a pharmacy benefit manager; (iii) a laboratory company; (iv) a pharmacy that primarily compounds drugs or primarily dispenses compounded drugs; (v) a manufacturer of a device or medical supply, as that term is defined in paragraph 1001.952(ee)(14)(iv) of this section; (vi) a medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supply, as defined in paragraph (ee)(14)(iv) of this section; or (vii) an entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services). We are not making payments made by pharmacies ineligible for safe harbor protection (except with respect to pharmacies that primarily compound drugs or primarily dispense compounded drugs for the reasons described in section III.B.2.e.ii.f above), although we suspect outcomes-based payments made by pharmacies might be relatively rare. As noted in a comment and response summarized in section III.B.2.e.iv above, pharmacies often serve as the key point of contact between patients and the health care system and provide many services to patients. For the same reasons we describe in that section, we do not believe that program integrity concerns warrant excluding them from protection under this safe harbor. We have modified the language describing DMEPOS companies to clarify that a pharmacy (other than a compounding pharmacy) or physician, provider, or other entity that primarily furnishes services remains eligible to make protected payments even if they also have some DMEPOS business. We did not propose, and did not intend, to exclude physicians or other providers.

We are mindful that there may be legitimate uses for outcomes-based payments by these sectors. However, we are concerned that the proposed safe harbor conditions were not intended to be, and are not, tailored to outcome-based contracting or payments in these sectors. As noted in the OIG Proposed Rule, we may consider outcomes-based contracting for pharmaceutical products and medical device manufacturers in future rulemaking. Outcomes-based payment arrangements involving these sectors should be analyzed for compliance with the Federal anti-kickback statute based on their facts and circumstances, including the intent of the parties. The entities that are ineligible to receive protection under this safe harbor for making outcomes-based payments remain eligible to use the modified personal services and management contracts safe harbor at paragraph 1001.952(d)(1).

[131] 84 FR 55746 (Oct. 17, 2019).

[132] 84 FR 55705 (Oct. 17, 2019).

[133] *Id.*

e. Writing and Monitoring

Summary of OIG Proposed Rule: With paragraph 1001.952(d)(2)(viii), we proposed a requirement of a signed writing evidencing the outcomes-based payments agreement. We proposed at paragraph 1001.952(d)(2)(vii) a requirement that the parties regularly monitor and assess the agent's performance for each outcome measure, including the impact of the outcomes-based payments arrangement on quality of care, and rebase outcomes measures periodically.

Summary of Final Rule: We are finalizing, with modifications, the writing requirement for outcomes-based payments and we moved the requirement from paragraph 1001.952(d)(2)(viii) to paragraph 1001.952(d)(2)(iii). As modified, the written agreement must include at a minimum a general description of the types of services to be performed under an outcomes-based payment arrangement. We are also finalizing the monitoring and assessment requirement with clarification regarding the rebasing requirement. Under the final rule parties must periodically assess and, as necessary revise, benchmarks and remuneration under the agreement to ensure that any remuneration is consistent with fair market value in an arm's-length transaction as required by paragraph 1001.952(d)(2)(ii).

Comment: Commenters generally agreed that some type of written agreement should be required for safe harbor protection, but commenters did not necessarily agree with the specific condition OIG proposed. On the one hand, a commenter was concerned about arrangements losing safe harbor protection by not technically meeting the requirement of all services being documented, considering the need for some arrangements to be flexible. On the other hand, a commenter recommended that the safe harbor include additional documentation requirements, such as: Documentation of benchmarking methodologies; metrics for how to assess objectively its outcome measure(s) and documentation of the execution of any such assessment; records created at the time they entered into the agreement identifying the basis for the determination of compensation and the clinical evidence or credible medical support considered; and contemporaneous documentation of the services performed and the outcomes achieved. This commenter asserted that these additional documentation requirements would help prevent post-hoc justifications for conduct that the parties did not actually believe was permissible at the time, and that a lack of documentation is a way individuals and entities try to hide lack of compliance with a safe harbor.

Response: We understand the need for flexibility in outcomes-based arrangements. However, the safe harbor must include safeguards to avoid protecting arrangements that reward referrals. In the OIG Proposed Rule, we proposed that the written agreement include at a minimum: (i) The services to be performed by the parties for the term of the agreement; (ii) the outcome measure(s) the agent must achieve to receive an outcomes-based payment; (iii) the clinical evidence or credible medical support relied upon by the parties to select the outcome measure(s); and (iv) the schedule for the parties to regularly monitor and assess the outcome measure(s). We believe it is critical for parties to include the outcome measures, the basis for selecting the outcome measures, and the monitoring and assessment schedule in an agreement at the outset of the arrangement.

However, we are modifying the requirement that the agreement specify the services to be performed over the term of the agreement. We recognize that the parties may not be aware of every step necessary to achieve a certain outcome measure when the agreement becomes effective and that the needed services might change over time to achieve the desired outcome measure. Protected remuneration under paragraph 1001.952(d)(2) is dependent upon meeting the outcome measure, not necessarily the specific steps a party may have taken to achieve that measure. Therefore, we are modifying the regulatory text to specify that the agreement must include at a minimum a general description of the types of services to be performed. We note, however, that other conditions of the safe harbor (*e.g.,* monitoring the arrangement to assess the agent's performance and impact on patient care) would necessitate some type of documentation of services or other activities performed to achieve the outcome measure. We believe that requiring a general description of the anticipated services, coupled with the other required elements of the written agreement, strikes the appropriate balance between transparency needed to protect patients and Federal health care programs and flexibility for parties to create innovative arrangements that may need to evolve to achieve the desired results.

Comment: A commenter asked whether an agreement to provide outcomes-based payments can be signed in advance of the establishment of the outcome measure(s) and whether the parties' eligibility for compensation commences on the date the outcome measure(s) are mutually agreed upon in writing signed by the parties or at some other time.

Response: There may be certain other existing written agreements between the parties in advance of commencing an outcomes-based payment arrangement. But for purposes of meeting the writing requirement for protection under this safe harbor, the parties must agree to the outcome measure(s) in writing and sign such an agreement in advance of, or contemporaneous with, the commencement of the terms of the outcomes-based payment arrangement. Furthermore, eligibility for protected compensation under this safe harbor commences after achievement of the outcomes measure (or failure to achieve it by the designated time in the case of a shared losses payment), assuming all safe harbor conditions are met.

11. Warranties (42 CFR 1001.952(g))

Summary of OIG Proposed Rule: We proposed to modify the existing safe harbor for warranties at paragraph 1001.952(g) to: (i) Protect certain warranties for one or more items and related services upon certain conditions, such as all federally reimbursable items and services subject to bundled warranty arrangements must be reimbursed by the same Federal health care program and in the same payment (''same program/same payment requirement''); (ii) exclude beneficiaries from the reporting requirements applicable to buyers; and (iii) define ''warranty'' directly and not by reference to 15 U.S.C. 2301(6).

Summary of Final Rule: We are finalizing the modifications to the warranties safe harbor as proposed in the OIG Proposed Rule. In addition, in response to concerns raised by commenters, we are clarifying in this preamble the scope of buyers' reporting obligations to make clear the safe harbor is designed to accommodate the various reimbursement systems under which buyers may report price reductions.

a. Inclusion of Services in Bundled Warranties

We are finalizing our proposal to protect warranties that warranty a bundle of items or a bundle of items and services. This revision protects, for the first time, warranties covering services, although the safe harbor does not provide protection to warranties that warranty only services. As explained in the OIG Proposed Rule, we believe warranties for services that are not tied

to one or more related items could present heightened fraud and abuse risks.

Comment: Commenters generally supported our proposal to revise the warranties safe harbor to protect bundled warranties for one or more items and related services. A commenter noted sellers and buyers, such as health systems, would have greater flexibility under the safe harbor to protect related services that are often integral to determining whether the terms of a warranty, such as a clinical outcome, have been met. According to the commenter, such services might include, for example, data collection and analytics, verification of product use consistent with labeling and governing clinical protocols (including through confirmatory laboratory testing), and monitoring patient adherence to prescribed treatment regimens.

Response: We agree with commenters that the revised safe harbor will offer greater flexibility to buyers and sellers to enter into innovative arrangements that warranty the value of an entire bundle of items or that include bundled items and services. We would highlight, however, that this revision to the warranties safe harbor does not protect free or reduced-priced items or services that sellers provide either as part of a bundled warranty arrangement or ancillary to a warranty arrangement. Instead, it merely protects the offer and exchange of warranty remedies under a warranty arrangement, provided all of the safe harbor's conditions are satisfied. As discussed further below, items and services provided either as part of or ancillary to a warranty arrangement may not need safe harbor protection or may be protected by other safe harbors.

Comment: A commenter supported our proposal not to protect warranties covering only services. Another commenter, however, recommended that OIG should protect warranties that cover services only, explaining that medical device manufacturers can play a role in offering data analytics via software solutions, for example to predict post-treatment health care conditions and costs and thereby reduce utilization of higher-acuity post-acute services. According to the commenter, offering warranties that guarantee outcomes from using such services would provide an incentive for investment from both parties—the vendor and the provider.

Response: We appreciate the commenter's explanation regarding the potential benefits of services offerings. As we discussed in the OIG Proposed Rule, however, we believe services-only warranty arrangements present a heightened risk of fraud and abuse. In particular, we noted that the determination of whether services meet a clinical outcomes goal established by a warranty arrangement can be more subjective than warranties involving items. We also expressed concern that the potential to receive a monetary remedy under a services-only warranty could induce patients to select a particular provider, particularly if the clinical results are not easily achievable. Parties seeking to enter into outcomes-based arrangements for only services may look to the revised personal services and management contracts and outcomes-based payment arrangements safe harbor at paragraph 1001.952(d) for potential protection.

Comment: A commenter requested that if OIG finalizes limitations on the items and services that may qualify for bundled warranties, OIG should clarify that a warrantied bundle of items and services could encompass limited support services offered by the manufacturer that are not federally reimbursable and are offered free of charge. The commenter asked for this clarification in light of preamble language from the OIG Proposed Rule stating that the modified safe harbor would not protect free or reduced-priced items or services that sellers provide either as part of a bundled warranty arrangement or ancillary to a warranty arrangement. As an example, the commenter asked OIG to confirm that the safe harbor would protect a manufacturer's warranty of the clinical effectiveness of a self-injected drug contingent on the patient receiving product administration and use education through nurse support offered by the manufacturer.

Response: We confirm that, under the safe harbor as modified, a warrantied bundle of items and services could encompass services offered by the manufacturer that are not federally reimbursable and are offered free of charge, although we emphasize that the safe harbor only protects remuneration provided as a warranty remedy; services offered for free by manufacturers would not themselves be protected under this safe harbor. The same program/same payment requirement does not prohibit the inclusion of non-federally reimbursable items or services in the bundle of items and services being warrantied. Therefore, under the safe harbor, a manufacturer could offer a bundled warranty that warranties the clinical effectiveness of a self-injected drug contingent on the patient receiving post-prescribing product administration and use education through nurse support offered by the manufacturer. We also want to confirm and clarify that the modified safe harbor does not protect free or reduced-priced items or services that sellers provide either as part of a bundled warranty arrangement or ancillary to a warranty arrangement. The modifications to the safe harbor provide protection for warranty remedies stemming from warranties covering more than one item or more than one item and service, whereas the original safe harbor for warranties provided protection for warranty remedies stemming from warranties on only one item. If non-reimbursable items or services offered for free as part of a bundled warranty have independent value to a buyer, the parties to the warranty arrangement may look to other safe harbors to protect the exchange of those items and services, such as the personal services and management contracts and outcomes-based payments safe harbor.

Comment: In response to our solicitation of comments regarding the potential anticompetitive effects that bundled warranties may have—including barriers to entry for manufacturers and suppliers that cannot offer bundled warranties—a commenter stated that it did not believe competitive barriers to entry were a likely outcome, and that any risks of anticompetitive behavior that may exist are better addressed through the government's other enforcement authorities to police anticompetitive behavior. According to the commenter, it is not uncommon for vendors to partner in selling and offering a warranty for a bundle of products containing items from different vendors.

Response: We appreciate this comment and recognize that a variety of models exist in the marketplace for bundled-sale arrangements. We are not finalizing additional safeguards designed to limit the potential anticompetitive effects of bundled warranties. We continue to believe, however, that anticompetitive risks can be reduced by the safe harbor's provisions prohibiting exclusive-use or minimum-purchase requirements as a condition of a warranty offering.

Comment: A commenter warned that bundled warranties may harm competition and limit clinician and patient choice because, even with the prohibition on exclusivity and minimum-purchase requirements, sellers could condition a warranty on the purchase of a bundle of products and services. The commenter suggested that OIG include language in the safe harbor that no warranty shall interfere

with a health care provider's autonomy and responsibility to make clinical decisions with regard to patient care and safety.

Response: We appreciate the commenters' concerns and recognize that providing protection for bundled warranties could result in some anticompetitive effects. However, the safeguards we are finalizing in this rule, including prohibiting exclusivity and minimum-purchase requirements and limiting the scope of what may be included in a bundled warranty, provide meaningful protection against anticompetitive behavior that otherwise may occur. As noted in the OIG Proposed Rule, protection for bundled warranties may foster beneficial arrangements that facilitate the use of higher-value items and services. While we have not included an express requirement that protected warranties cannot interfere with a health care provider's autonomy and responsibility to make clinical decisions with regard to patient care and safety, we emphasize that the modifications to the safe harbor that we are finalizing are not intended to—and should not—affect providers' ongoing responsibilities to make clinical decisions in the best interests of their patients.

Comment: Some commenters recommended that we include other additional safeguards within the safe harbor. For example, a commenter urged OIG to consider a safeguard that would prohibit any unfair or deceptive practice in the marketing of a service warranty. Another commenter urged us to add a requirement that for a warranty to be protected under the safe harbor, the manufacturer or supplier must determine that the warranty is reasonably related to an evidence-based clinical improvement objective and is commercially reasonable.

Response: As noted above, we believe the safeguards in the OIG Proposed Rule strike the right balance between protecting beneficiaries and Federal health care programs while promoting beneficial and innovative arrangements, such as bundled warranties. In particular, we have not added a separate prohibition against unfair or deceptive practices because deceptive commercial practices are already prohibited by numerous State and Federal laws. We do not believe providing a separate requirement here is necessary.

We also decline to impose a requirement that warranty arrangements relate to evidence-based clinical improvement objectives. Although some warranties may relate to evidence-based clinical improvement outcomes, many warranty arrangements that the safe harbor could protect, such as those guaranteeing that an item is defect-free or otherwise functions as intended, may not have an evidence-based clinical improvement component.

Finally, we decline to impose a commercial reasonableness requirement within the warranties safe harbor for the same reasons articulated above. It is not clear that a commercial reasonableness requirement would provide additional, meaningful protection against fraud and abuse in the context of the warranties safe harbor, given the limited scope of protected remuneration and, in particular, that a seller may not pay any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty.

Comment: Some commenters opposed restrictions on the manner in which sellers could provide warrantied medication adherence services as part of a bundled warranty, with those commenters pointing to the importance of medication adherence services generally and the alignment that exists between manufacturers' incentives and patients' health outcomes. Commenters noted that adherence programs can play an important role in helping patients follow their prescribed treatment regimens, which has been shown to lead to better patient outcomes, including fewer hospitalizations and emergency room visits. Commenters also pointed out that medication nonadherence—the problem of patients not taking medications in accordance with their health care providers' directions or otherwise not following their providers' treatment recommendations—is a major health problem, leading to poor clinical outcomes and increased health care spending. Commenters also asserted that the fraud and abuse risks of manufacturers providing medication adherence services is low because manufacturers have financial, regulatory, reputational, ethical, and legal incentives to ensure their products are used only to the extent that they continue to be safe and effective for patients. Commenters further noted that, when medication adherence programs are included in outcomes-based contracts, manufacturers are rewarded for their product working as intended to promote patients' health and safety and penalized for their product not working well for patients, which improves the alignment between manufacturer incentives and patient health and safety.

Although most commenters on the topic did not support restrictions on the manner in which sellers could provide warrantied medication adherence services, a few commenters expressed support for a possible safeguard discussed in the OIG Proposed Rule. In particular, a commenter expressed support for OIG's proposal to require sellers' use of independent intermediaries for direct patient adherence activities, while another commenter supported a prohibition on any direct patient outreach by a seller offering a warranty. A commenter who shared the concerns expressed in the OIG Proposed Rule regarding patient outreach services being provided by manufacturers and suppliers recommended a safeguard requiring that warrantied patient outreach services be approved by a licensed medical professional. In doing so, the commenter expressed concern that drug manufacturers may abuse any safeguard requiring sellers to use independent intermediaries to perform direct patient outreach services.

Response: OIG agrees that medication adherence services can have a significant beneficial impact on patient health and health care costs. Although we also recognize the potential for greater alignment of manufacturers' incentives and patient health outcomes in value-based arrangements, at this time most arrangements for the sale of a drug reimbursed by a Federal health care program are not outcome-driven, and we continue to have concerns regarding the direct provision of medication adherence services by sellers of warrantied items because their financial incentive to sell their products could result in medication adherence services that increase fraud and abuse risks, such as patient harm and overutilization.

Despite these risks, we are not imposing any restriction in this final rule on the manner in which warrantied medication adherence services may be provided when offered as part of a bundled warranty. A limitation on the manner in which sellers of one or more warrantied items provide such services as part of a bundled warranty may not materially reduce any fraud and abuse risks, particularly because a limitation on warranties would not affect the provision of medication adherence services in contexts other than bundled warranties. For the same reason, we are declining to impose a requirement that warrantied medication adherence services must either be provided via an independent intermediary or subject to the approval of a licensed medical professional. We emphasize that the warranties safe harbor would not protect the provision of free or reduced-cost

medication adherence services furnished by a seller.

Comment: A few commenters asserted that, consistent with existing OIG guidance, medication adherence services do not constitute remuneration because they do not have independent value to a buyer but rather are integrally related to the underlying product. A commenter noted that, although OIG has expressed concern that manufacturer-sponsored adherence supports could replace actions that a health care provider might otherwise take to support medication adherence, the likelihood of manufacturer adherence supports leading providers to reduce their own efforts to improve their patients' medication adherence is very small.

Response: We disagree with the assertion that medication adherence services never constitute remuneration and thus never implicate the anti-kickback statute. For example, in Advisory Opinion No. 11–07, we noted that the vaccine reminder program offered by a manufacturer could have independent value to health insurers and health care entities and could confer an additional financial benefit on physicians because the vaccine reminders were intended to encourage the recipients to schedule an appointment with their children's health care practitioners, who likely would be reimbursed for administering the vaccine and possibly for an associated office visit. As highlighted in this example, medication adherence services could result in a provider's opportunity to earn income. We also recognize that medication adherence services provided to beneficiaries as part of warranty arrangements could have independent value to the beneficiary, depending on how those arrangements are structured.

Although the OIG Proposed Rule stated that the provision of free or below fair market value medication adherence services ''would implicate the anti-kickback statute,'' [134] we clarify in this final rule our position that such services could implicate the statute but would not necessarily implicate the statute in all circumstances, and that such analysis would be dependent upon the facts and circumstances of a specific offering.

Comment: A commenter urged OIG to ensure that pharmacies can continue to provide adherence and medication therapy management services, including when such activities are compensated at fair market value by payors, manufacturers, and others within the supply and payment chain.

Response: The modifications to the warranties safe harbor set forth in this final rule do not change pharmacies' ability to provide adherence and medication therapy management services. Any financial arrangement between pharmacies and payors, manufacturers, and others within the supply and payment chain could implicate the anti-kickback statute and should be analyzed on a case-by-case basis for compliance with the statute. Depending on the facts, other safe harbors may be available, including the personal services and management contracts and outcomes-based payments safe harbor.

Comment: A commenter expressed support for a standalone safe harbor protecting manufacturer-supported patient adherence programs, and other commenters asked OIG to promulgate an additional rule that expressly defines how value-based arrangements for drugs can include all relevant health care entities (including manufacturers, payors, providers, and patients) and medication adherence programs without running afoul of the Federal anti-kickback statute.

Response: We appreciate the commenters' requests for further rulemaking. However, they are outside the scope of this rulemaking.

Comment: A commenter expressed concern regarding the statement in the OIG Proposed Rule regarding the provision of free or reduced-price laboratory testing as part of a warranty arrangement. The commenter asserted that the inclusion of confirmatory laboratory testing under a warranty arrangement could fit within the revised warranties safe harbor where a seller engages an independent laboratory under a fair market value arrangement to perform testing solely to determine whether the terms of a clinical outcome or other value-based warranty have been met.

Response: Regardless of whether items and services used to determine the efficacy of a warranty have independent value to the buyer, the warranties safe harbor provides protection only for sellers' offer and provision of warranty remedies, not the offer or sale of the items and services being warrantied or any items or services used to determine whether a clinical outcome or other value-based outcome has been achieved. We recognize that warranty arrangements in some circumstances may require laboratory testing or other data to determine, for example, whether clinical or other outcomes have been met or whether the buyer or patient has adhered to the terms of the warranty.

We did not intend to suggest in the OIG Proposed Rule that, in all instances, confirmatory laboratory testing for purposes of determining whether warrantied outcomes have been achieved would implicate the anti-kickback statute. Where a seller provides free items and services ancillary to a warranty arrangement that could have independent value to the buyer, sellers should analyze such arrangements on a case-by-case basis to determine whether they implicate the anti-kickback statute and may look to other safe harbors, such as the safe harbor for personal services and management contracts and outcomes-based payments, for protection. In the case of confirmatory laboratory testing relating to a warranty arrangement, such testing could have independent value to the buyer if, for example, it alleviates administrative or financial burdens the buyer otherwise would incur to obtain laboratory testing for purposes other than the warranty.

b. Requirement for Federally Reimbursable Items and Services Subject to Bundled Warranty Arrangements To Be Reimbursed by the Same Federal Health Care Program and in the Same Payment

We recognize the possibility that bundling of one or more items and related services that are reimbursed under different methodologies or different payments could create incentives for overutilization or the potential for cost-shifting. The final rule protects warranties that apply to one or more items and related services only if the federally reimbursable items and services subject to the warranty arrangement are reimbursed by the same Federal health care program and in the same Federal health care program payment. The same program/same payment requirement provides important protection against these risks.

Comment: A number of commenters objected to the condition that federally reimbursable items and services in a bundled warranty arrangement must be reimbursed by the same Federal health care program and in the same Federal health care program payment in order to qualify for protection under the safe harbor. Commenters expressed concern that this condition would constrain innovation by limiting what items may or may not be included in a bundle based on reimbursement status, rather than focusing on clinical efficacy. A trade association representing providers noted that care coordination arrangements often require payments

[134] 84 FR 55748 n.83 (Oct. 17, 2019).

from different reimbursement methodologies. For example, a joint replacement can occur in a hospital or ambulatory surgical center and then a patient may be discharged to a skilled nursing facility or to home health care. The commenter expressed concern that a warranty covering this episode of care would not be eligible for safe harbor protection because of the different payment methodologies. The commenter recommended OIG implement alternative safeguards in lieu of the same program/same payment requirement, such as limiting application of the safe harbor to medically necessary items and services, prohibiting stinting, and requiring the warranty to be part of a written care plan by a licensed medical professional.

Other health care providers commented that the proposed same program/same payment requirement is outdated and unworkable in light of value-based arrangements that utilize a combination of items, services, or both, and that it is impracticable to determine that the same program/same payment requirement will be satisfied for every patient. Commenters also noted that warranties allow manufacturers to help providers manage risk when testing out new combinations of devices and supports, even if they are reimbursed under separate prospective or composite rate systems.

Response: Although the warranties safe harbor could be used to protect a wide range of innovative arrangements, it is not designed to protect warranties involving items purchased by multiple buyers across different care settings or reimbursed by different payment systems. As explained further in this final rule, we believe a bundle of products paid for separately and potentially across different payment systems poses an increased risk of inappropriate utilization and overutilization. Such arrangements may qualify for protection under the value-based safe harbors described in this final rule, such as the safe harbors for care coordination arrangements (paragraph 1001.952(ee)), value-based arrangements with substantial downside financial risk (paragraph 1001.952(ff)), and value-based arrangements with full financial risk (paragraph 1001.952(gg)). We do not believe that the proposed alternative safeguards would be as effective—or as straightforward to apply and interpret—as the same program/same payment requirement we are finalizing.

Comment: A commenter noted that a manufacturer or supplier seldom knows all of the ways in which providers might be reimbursed for items and services included in a bundled warranty arrangement.

Response: As noted above, the warranties safe harbor is not designed to protect warranty arrangements that span different care settings or that involve multiple payment systems. Sellers should be able to craft warranty offerings that meet the terms of the safe harbor, even if a particular bundle of items or items and services could potentially be reimbursed in different ways. For example, a seller's written warranty could specify that warranty remuneration is available only in circumstances in which the bundle is reimbursed under the same Federal health care program and in the same payment.

Comment: Commenters noted that the bundled warranty arrangement approved under Advisory Opinion No. 18–10 would not meet the revised safe harbor because some of the items in the bundle were separately reimbursable under certain States' Medicaid programs. Commenters also observed that various State Medicaid programs employ different reimbursement methodologies and that even within a single State, reimbursement methodologies can differ depending on whether beneficiaries are covered by the State's fee-for-service program or a Medicaid managed care plan.

Response: We acknowledge that Medicaid programs reimburse items and services with a variety of payment methodologies, which can include separate, unbundled reimbursement for some items. We remain concerned, however, that providing safe harbor protection to warranties containing separately reimbursable items would introduce a higher risk of fraud and abuse in the form of potential overutilization, inappropriate steering, or inappropriate utilization. For example, a buyer may have an incentive to purchase separately reimbursable items in order to receive the benefit of a warranty on those items because the buyer will be reimbursed for each item separately, and if even one item does not meet the specified level of performance, the buyer could receive the cost of all items in the bundle. By comparison, if a buyer receives one warranty payment for all items covered by a bundled warranty, the buyer has a greater incentive to contain its costs and not purchase unnecessary items (or services).

The arrangement described in Advisory Opinion No. 18–10 included the possibility that bundled devices could be separately reimbursed by State Medicaid programs, although the opinion specified that these instances would be infrequent and that Medicaid-reimbursed cases represented a very small part of the requestor's business. Although warranty remuneration paid resulting from the failure of a separately reimbursable item or service would not be covered by the warranties safe harbor, the advisory opinion process remains available for a legal opinion regarding facts and circumstances that may not be protected by the safe harbor.

Although we solicited comments on instances when an exception may be necessary to the provision requiring reimbursement by the same Federal health care program payment, upon further consideration we do not believe an exception is necessary. The modified safe harbor requires that federally reimbursable items and services covered by a bundled warranty must be reimbursed by the same Federal health care program payment—not that the items and services be only reimbursable by one Federal health care program payment. In other words, the possibility that an item or service is reimbursable under a different program or by a different payment does not foreclose a manufacturer or supplier from offering a bundled warranty covering the item or service as long as the item or service is in fact reimbursed by the same Federal health care program payment as the other item(s) and service(s) comprising the warranty bundle.

Although we recognize that it may be difficult for a seller to know under which reimbursement methodology a particular item or service will be reimbursed, we believe parties entering into bundled warranty arrangements could specify in the warranty's written terms that only items and services reimbursed by the same Federal health care program payment will be eligible for the warranty. Because warranty remedies are by their nature furnished after the use of items and services, a buyer likely knows before making a warranty claim whether the items and services are or will be reimbursed by the same Federal health care program payment. Consequently, a warranty undertaking could explicitly state that warranty remedies are available only for patients or procedures in which the bundled items and services are reimbursed by the same program and same payment even where alternative reimbursement methodologies for those items and services exist.

Comment: A commenter noted that in many cases items or services included in a bundle are not reimbursed specifically but might be deemed reimbursed indirectly as part of a payment for another item or service. In such cases, there might be numerous

potential payments or reimbursement methodologies which could be viewed as providing such indirect reimbursement.

Response: The warranties safe harbor does not attempt to address every possible variation in reimbursement methodologies. We continue to believe that limiting safe harbor protection to warranties involving bundled items and services reimbursed under the same program and same payment is an important safeguard to protect against inappropriate steering, inappropriate utilization, or overutilization of federally reimbursable health care items and services. We believe that, in most circumstances, health care providers can identify the reimbursement source for a particular item and can also determine whether items and services subject to a bundled warranty are reimbursed by the same payment.

Comment: A commenter urged OIG to abandon the same program/same payment requirement and instead extend protection for bundled warranties involving items and services reimbursed under multiple prospective payment or composite rate systems, which the commenter asserted would protect a broader range of warranties but pose a low risk of fraud and abuse due to cost-shifting because no warrantied items would be separately reimbursable. Another commenter suggested that the safe harbor should protect bundled warranties involving items and services that are not specifically reimbursed under bundled or fee-for-service payments but that could be reflected in some manner in a provider's Medicare cost report.

Response: Although we recognize that warrantying only bundled items and services reimbursed under prospective payment bundles or composite rate systems could reduce the risk of cost-shifting between Federal health care programs, we remain concerned that protecting bundled warranties across such methodologies could complicate both the administration of warranties and reporting obligations, and we decline to expand the safe harbor provision according to the commenter's suggestion.

Comment: A commenter stated that the same program/same payment requirement would not protect a warranty bundle consisting of a particular federally reimbursed drug product when used in conjunction with a companion diagnostic. According to the commenter, the drug would be reimbursed under Medicare at the negotiated price (for a Part D drug) or at ASP plus 6 percent (for a Part B drug), while the companion diagnostic would be reimbursed under the clinical laboratory fee schedule.

Response: We appreciate the commenter's concern and acknowledge that the safe harbor would not protect the type of arrangement described in this comment. However, the safe harbor could protect a warranty covering a drug product, and where the seller wants to provide a companion diagnostic to determine if a warrantied outcome has been achieved, the seller could look to other safe harbors to protect the provision of the companion diagnostic to the extent the provision of the companion diagnostic implicates the anti-kickback statute.

Comment: A commenter asserted that the same program/same payment requirement could foreclose protection for even one-drug warranties because drugs are virtually always reimbursed by Medicare, Medicaid (and usually additional Federal health care programs), with each program having different payment methodologies for outpatient drugs.

Response: As noted in proposed paragraph 1001.952(g)(5), the same program/same payment requirement would only apply when a manufacturer or supplier offers a warranty for more than one item or one or more items and related services. This requirement would not apply to single-item warranties.

Comment: A number of commenters expressed concern that the requirement that federally reimbursable bundled items and services be reimbursed by the same Federal health care program payment could inhibit innovative warranties based on the performance of warrantied items and related services across a patient population (population-based warranties). A commenter argued that the safe harbor should accommodate value-based arrangements that study a representative sample of a patient population and use the results observed from the sample to determine the price or price concession that is appropriate for product utilization more broadly. Another commenter asserted that warranties offered across a patient population have a low risk of fraud and abuse where none of the items or services is separately reimbursable.

Response: As discussed in the preamble to the OIG Proposed Rule, we believe the expanded warranties safe harbor will facilitate beneficial and innovative arrangements between buyers and sellers, such as bundled warranties. While population-based warranties would not necessarily pose the same fraud and abuse risk of problematic cost-shifting between Federal health care programs as warranties covering a bundle of items and services that are reimbursable under different Federal health care programs, population-based warranties could pose different fraud and abuse risks. Specifically, population-based warranties may result in steering to particular products in a manner that inappropriately limits patient choice and providers' clinical decision-making and could result in overutilization or inappropriate utilization of items or services where a buyer feels compelled to use a certain quantity of a seller's product in order to be eligible for a warranty remedy. We appreciate the commenter's request for the warranties safe harbor to protect value-based arrangements that could inform the price of a product, and while the modified safe harbor does not specifically protect population-based warranties, we emphasize our statement in the OIG Proposed Rule that we may consider specifically tailored safe harbor protection for value-based contracting and outcomes-based contracting for the purchase of pharmaceutical products (and potentially other types of products) in future rulemaking.

c. Capped Amount of Warranty Remedies

The existing safe harbor for warranties contains the limitation that a manufacturer or supplier must not pay remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself. In the OIG Proposed Rule, at proposed paragraph 1001.952(g)5), we proposed to adapt this limitation to accommodate the safe harbor's expanded protection of bundled warranties. In the modifications to the safe harbor we are finalizing here, warranty remuneration for any medical, surgical, or hospital expense incurred by a beneficiary is capped at the cost of the items and services subject to the warranty.

This cap plays an important role in safeguarding against sellers providing excess remuneration to providers to induce referrals. The revised safe harbor offers sellers more flexibility by protecting both a broader scope of warranties and a potentially higher amount of warranty remuneration reflecting the cost of the entire bundle of items or bundle of items and services. This adaptation allows sellers to offer a valuable remedy to their customers if a product fails to meet a specified level of performance.

Comment: Although some commenters expressed support for OIG's proposal to limit the remuneration a

manufacturer or supplier may pay to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of items and services subject to the warranty, several commenters objected to this proposed safeguard. For example, a commenter argued that warranty remedies that exceed the aggregate value of the warrantied items and related services are likely to be the key drivers in realizing the potential of value-based care. Another commenter stated that capping the warranty remedy based on the collective cost of the warrantied items and services is insufficient because providers expect vendors offering warranties addressing long-term population health issues to be financially accountable for costs greater than the cost of the items and services subject to the warranty.

Response: As proposed, the revised safe harbor would protect warranties in which vendors offer to reimburse any medical, surgical, or hospital expense incurred, up to the cost of the warrantied items and services incurred by the buyer to acquire those items and services. The safe harbor could be used to protect reimbursement for hospital expenses incurred as a result of, for example, a bundle of items that failed to meet the clinical outcomes guaranteed by a warranty arrangement. The total warranty remuneration provided, however—including the cost of any replacement items—would be limited to the original cost of the items and services incurred by the buyer. We believe the proposed expansion of this safe harbor provides a significant and sufficient opportunity for vendors to offer a meaningful and valuable remedy to their customers to account for the failure of an item, a bundle of items, or a bundle of items and services to meet warrantied standards.

Comment: Commenters stated that capping the amount of warranty remuneration will negatively impact patient care and unnecessarily stifle innovative value-based arrangements because vendors will not be able to offer appropriate remedies if warrantied outcomes are not achieved, such as the provision or payment for medical, surgical, hospital, or other services and related items in connection with the replacement or supplementation of a warrantied item, or as an alternative or supplemental treatment.

Response: We continue to believe that the proposed cap strikes an appropriate balance between protecting remuneration for warrantied products and safeguarding against excessive remuneration paid by vendors to induce referrals. Furthermore, as we explained in the preamble to the OIG Proposed Rule, the safe harbor, as finalized, already is broad enough to protect certain value-based arrangements, such as warranties that offer a clinical outcomes guarantee, as long as the safe harbor's other requirements are met.

Comment: A commenter stated that there is negligible risk that manufacturers and suppliers would use warranties to provide excess remuneration because vendors entering into warranty arrangements face steep exposure and will take all possible precautions to avoid future payments under such warranties.

Response: We continue to believe that without limiting the amount of protected warranty remuneration there is a risk of vendors paying excessive remuneration to induce further Federal health care business. For example, without a cap on warranty remuneration, a vendor could pay for a wide range of consequential expenses resulting from the failure of a device including, for example, hospitalization expenses, revision surgery, and other downstream expenses, in addition to providing a replacement for the faulty device. We believe that would provide too great an opportunity for sellers to offer generous remuneration to buyers.

d. Prohibition on Exclusivity and Minimum-Purchase Requirements

We proposed a new safeguard at proposed paragraph 1001.952(g)(6) that would preclude warranty arrangements from being conditioned on the exclusive use or minimum purchase of one or more items or services. We are finalizing this safeguard because we believe it provides important protection against patient steering that could interfere with clinical decision-making and against potential anticompetitive effects.

Comment: Some commenters expressed support for the proposed prohibition on warranties conditioned on a buyer's exclusive use of any of the manufacturer's or supplier's items or services. Other commenters argued that these safeguards are unnecessary and possibly contravene the intent of the proposal. For example, a commenter noted that warranties constitute a means by which sellers compete against one another by providing assurances of performance. In addition, commenters noted that providers can standardize their use of any one of a number of similar, competitive products, and that such standardization through exclusivity and minimum-purchase requirements can promote competition and lower costs without triggering any concerns regarding patient access to medically necessary items.

Response: We are finalizing the prohibition against sellers conditioning a warranty on a buyer's exclusive use or minimum purchase of any of the seller's items or services. Although exclusivity and minimum-purchase requirements may allow for certain efficiencies, we view exclusivity and minimum-purchase requirements tied to the offer of a warranty as potentially abusive steering practices that could result in, among other things, interference with clinical decision-making, overutilization or inappropriate utilization, or anticompetitive effects. Because warranty arrangements can be valuable tools for buyers to defray the costs associated with an item (and under the modified safe harbor, multiple items or items and services) that does not function as expected, the potential for sellers to require exclusivity and minimum-purchase requirements in exchange for a warranty may lock buyers into a particular item (and under the modified safe harbor, multiple items or items and services) and thereby could result in, for example, a buyer using a particular item in a given case that is not in the patient's best interest.

Comment: A commenter asserted that exclusivity and minimum-purchase requirements are features that can promote competition and lower costs, as in the case of purchase discounts conditioned on the volume of products purchased. The commenter observed that a warranty might be conditioned on a minimum- or exclusive-purchase requirement, and that such requirement would not preclude a buyer from purchasing competitive products in violation of the requirement; the provider would simply lose the benefit of the warranty by doing so.

Response: Because warranties can be valuable tools for buyers to defray the costs associated with an item (or items and services) that do not function as expected, we reiterate our concerns that conditioning warranties on exclusivity or minimum-purchase requirements increases certain fraud and abuse risks, as described above, and thus we are finalizing the modifications to the safe harbor with the prohibition on conditioning warranties on such requirements.

Comment: A number of commenters urged OIG to omit or revise the prohibition against conditioning warranties on minimum-purchase or exclusivity requirements. In particular, commenters asserted that population-based warranties typically require that there be some minimum level of use of the product (and any related services) so

as to make the outcomes measure statistically meaningful. For example, a manufacturer might state in a warranty, consistent with clinical studies, that use of its device will produce the warrantied outcome a given percentage of the time, but that the warranty is only available if the device has been used on a large enough number of patients (typically determined through a minimum-purchase requirement) to produce a statistically relevant outcomes measure.

Response: We agree that population-based warranties could require a certain amount of use of a product and any related services to make the outcomes measure(s) set forth in a warranty undertaking statistically meaningful. However, for the reasons set forth in this preamble, we are finalizing the same program/same payment requirement, which means that protection under the safe harbor as modified does not extend to warranties for items used across a patient population. Particularly given this limitation in the safe harbor, we do not believe conditioning warranties on exclusivity or minimum-purchase requirements is necessary for sellers to engage in beneficial warranty arrangements that promote the value of the items and services being warrantied.

Comment: A commenter urged OIG to adopt a permissive approach, which would protect warranties conditioned upon exclusive-use arrangements under the safe harbor as long as manufacturers or suppliers: (i) Have good-faith reasons for adopting exclusive-use requirements; (ii) take and document reasonable precautions to avoid stinting on care, cherry-picking, lemon-dropping, or inappropriate utilization; and (iii) otherwise ensure that neither clinical decision-making nor patient care choices are adversely impacted.

Response: We appreciate the commenter's recommended safeguards and the commenter's focus on reducing the fraud and abuse risks associated with exclusivity requirements. However, for the reasons articulated above, we view certain risks as an inherent part of warranties conditioned on the exclusive use of any of a seller's products or services, and thus we are finalizing a safe harbor provision restricting warranties conditioned on exclusivity requirements.

Comment: Commenters noted that sellers of items reimbursed under Federal health care programs are not subject to any general prohibitions on imposing exclusivity or minimum-purchase requirements as a condition of making discounts available or otherwise.

Response: To the extent that the commenter refers to the discount safe harbor and the warranties safe harbor, those safe harbors were designed to protect remuneration paid under different circumstances, and therefore it is appropriate to include different safeguards in the safe harbors.

Comment: A number of commenters asserted that many of the innovative, risk-based warranty arrangements proposed by manufacturers may include equipment and consumables that must be used together, resulting in a requirement to exclusively utilize a manufacturer's goods in order to obtain warranty protection. The proposed limitation on exclusive use could hinder these manufacturers from creating and proposing such warranty-based risk-sharing arrangements.

Response: The revised warranties safe harbor, consistent with the description in the OIG Proposed Rule, would expand the safe harbor to explicitly protect warranties in which a bundle of items or a bundle of items and services must be used together to obtain warranty protection. The exclusive-use and minimum-purchase prohibitions provide meaningful protections against inappropriate steering practices and anticompetitive effects without impacting the ability of manufacturers and suppliers to offer bundled warranties.

Comment: A commenter requested clarification on how OIG will interpret the exclusive-use limitation if, for example, a provider enters into an arrangement to purchase an ''exclusive'' or ''preferred'' product independent of any potential unrelated bundled warranty offered by the product's manufacturer.

Response: OIG is aware that arrangements exist in which providers agree to the exclusive purchase of a particular item or designate an item as ''preferred'' in exchange for favorable commercial terms. The revised safe harbor is not intended to impact those arrangements. Rather, the exclusive-use and minimum-purchase provisions in the revised safe harbor prevent a manufacturer or supplier from receiving safe harbor protection for a warranty that is conditioned on the buyer's exclusive use or minimum purchase of items or services offered by the manufacturer or supplier. We interpret the ''conditioned on'' standard to mean that a causal connection exists between receiving a warranty (or continuing eligibility for warranty coverage) and maintaining exclusivity or minimum-purchase levels. The safe harbor does not prohibit exclusive-use or minimum-purchase provisions that are conditioned upon commercial terms unrelated to the offer of a warranty.

e. Reporting Requirements

As discussed in the OIG Proposed Rule, industry stakeholders have expressed concern that the safe harbor's existing reporting requirement could limit the ability of sellers to offer innovative warranty arrangements, including warranties that span multiple years. Stakeholders also have noted that the reporting requirement could make safe harbor protection unavailable for providers that lack specific reporting obligations under Federal health care programs or providers that do not file cost reports.

We are addressing these concerns in this final rule by: (i) Clarifying in the preamble discussion below that the safe harbor can be used to protect warranty arrangements that span multiple years; (ii) changing references in the safe harbor from ''the price reduction'' to ''any price reduction'' to make clear that more than one price reduction may occur pursuant to a warranty arrangement; and (iii) clarifying in this preamble that buyers are obligated to report price reductions in a manner compatible with the reimbursement methodology for the warrantied items or services, including circumstances in which a provider does not submit cost reports or a formal ''claim for payment'' unless the payor does not provide a reporting mechanism. Lastly, we are making a technical, non-substantive correction to paragraph 1001.952(g)(3) to remove a comma after ''and'' and before ''when any price reduction becomes known.''

Comment: A commenter noted that many items and services are reimbursed by Medicare Advantage plans or Medicaid managed care organizations, and therefore buyers have no obligations to report price reductions in a ''cost reporting mechanism'' or ''claim for payment,'' as referenced in the warranties safe harbor. The commenter asked OIG to clarify that a buyer should only be required to report a price reduction or replacement product obtained as part of a warranty if it has an obligation to do so under applicable requirements of the Federal health care program payor making payment for the warrantied item or service to which the price reduction relates.

Response: In the preamble to the OIG Proposed Rule, we solicited comments on the burden of current reporting requirements and the need for more flexible reporting requirements for warranties tied to clinical outcomes. We emphasize that buyers, other than beneficiaries, are obligated under the

safe harbor to report price reductions in a manner compatible with the reimbursement methodology for the item(s) or service(s) which, as a commenter pointed out, may not in all circumstances be reported in a ''cost reporting mechanism'' or a ''claim for payment.'' We affirm that this requirement applies to buyers even when buyers do not have an express obligation to report a price reduction or replacement product under applicable requirements of the Federal health care program payor making payment for the warrantied item or service to which the price reduction relates. In the event that a payor does not provide any mechanism for reporting of costs, such reporting is not required in order for a buyer to obtain safe harbor protection.[135]

Comment: In light of our preamble discussion regarding the timing of reporting requirements, including the protection for outcomes-based warranty arrangements in which buyers could receive return payments from manufacturers over several years, commenters requested additional clarification with respect to reporting requirements. In particular, commenters requested clarification that multiple warranty payments related to the same item or bundle of items and services could be reported at various points throughout a warranty arrangement, and that buyers are obligated to report such payments at the time they are received. A commenter suggested that OIG revise the manufacturer reporting requirements such that price reductions must appear either on an invoice or a statement, or on a series of invoices or statements. The commenter also suggested revising paragraph 1001.952(g)(3)(ii) such that the manufacturer is obligated to provide the buyer with documentation of the price reduction calculation in the same fiscal year as the purchase or the following fiscal year.

Response: We agree with the commenters that, under the warranties safe harbor, buyers can report multiple warranty payments related to the same item or bundle of items and services at various points throughout a warranty arrangement. Paragraph 1001.952(g)(1) already requires buyers to report ''any price reduction'' obtained as part of the warranty. We are finalizing corresponding revisions to paragraph 1001.952(g)(3) to change all references to ''the price reduction'' to ''any price reduction'' to make clear that more than one price reduction may occur pursuant to a warranty arrangement. With respect to the commenter's suggestion to allow sellers to report price reductions on a series of invoices or statements, we believe this expansion of the safe harbor is unnecessary because sellers must either: (i) Report price reductions on the initial invoice or statement the manufacturer sends to the buyer; or (ii) when the amount of any price reduction is not known at the time of sale, report the existence of the warranty on the invoice or statement, and later provide the buyer with documentation of the calculation of any price reduction resulting from the warranty. Therefore, sellers must provide information regarding all price reductions to the buyer regardless of whether sellers report them on an invoice or statement or otherwise. Lastly, the modifications to the warranties safe harbor set forth in this final rule do not include a requirement for the seller to provide the buyer with documentation of the price reduction calculation in the same or following fiscal year of the buyer. We expect buyers and sellers to fulfill their reporting obligations under paragraphs 1001.952(g)(1) and 1001.952(g)(3) in a timely manner but are not otherwise prescribing a timeline for doing so.

Comment: A commenter requested clarification that buyers are entitled to use any reasonable methodology for purposes of allocating a rebate that does not relate to a specific item or service across all bundled items and services to which the warranty rebate relates.

Response: We understand that, in some circumstances, remuneration paid pursuant to a bundled warranty will be related to more than one item or service that fails to meet the specifications set forth in the warranty undertaking. The safe harbor does not set forth a specific methodology to allocate reporting across multiple items or a combination of items and services. OIG believes that in most cases a warranty remedy paid pursuant to a bundled warranty should be reported proportionately to the cost of each bundled item or service, but we wish to provide flexibility for buyers to adopt different but reasonable allocation methodologies in circumstances in which, for example, the failure of the bundle to meet the agreed specifications results disproportionately from the failure of a particular item or service.

Comment: A commenter supported the proposal to expressly exclude beneficiaries from the reporting requirements applicable to other buyers.

Response: We appreciate the commenter's support, and we are finalizing revisions to the warranties safe harbor to exempt beneficiaries from the reporting requirement for buyers.

Comment: A commenter noted that a cost reduction under a warranty might be received long after the warrantied item has been purchased by a provider, particularly when the clinical outcome from the use of the item may be measured several years after the initial purchase of the item. Accordingly, the commenter recommended that OIG specifically provide for safe harbor purposes that such a rebate must be reported only after it is received.

Response: We agree that the reporting requirement is not triggered until remuneration is received under the warranty arrangement. We also recognize that the failure of an item or service to meet specifications might not occur until a period of years after purchase.

f. Definition of ''Warranty''

We proposed and are finalizing at paragraph 1001.952(g)(7) to define ''warranty'' directly and not by reference to 15 U.S.C. 2301(6). By defining ''warranty'' directly, we clarify that the warranties safe harbor is available for drugs and devices regulated under the Federal Food, Drug, and Cosmetic Act, whereas the definition set forth in 15 U.S.C. 2301(6) potentially excludes FDA-regulated drugs and devices. The safe harbor protects not only warranties covering a ''product'' but warranties covering an item or bundle of items, or services in combination with one or more related items. Finally, the new definition parallels the prior definition's language requiring a written promise that an item, bundle of items, or bundle of items and services is defect-free or will meet a specified level of performance over a specified period of time.

As we explained in the OIG Proposed Rule, we interpret the definition of ''warranty'' to apply to warranty arrangements conditioned on clinical outcomes guarantees, provided other safe harbor requirements are met.

Comment: Commenters expressed support for the proposed revisions to the warranties safe harbor, including adopting a new definition of the term ''warranty.'' Several commenters offered proposed revisions to the types of remuneration articulated in proposed

[135] We remind parties to warranty arrangements that they must comply with all legal obligations associated with Medicare cost reporting and other applicable requirements of any Federal health care program payor, including those related to billing and payment for replaced devices offered without cost or with a credit. For example, we note that under the Medicare inpatient prospective payment system if a provider received full credit for the cost of a device, CMS requires that the credit be reported to the Medicare program and the cost of the device is subtracted from the DRG payment. *See* 42 CFR 412.89; 42 CFR 412.2(g) and Medicare Claims Processing Manual, CMS Pub. 100–04, Ch. 3, § 100.8.

paragraph 1001.952(g)(7)(ii). In particular, commenters urged OIG to confirm that a partial refund or retrospective rebate resulting in a price adjustment would constitute a ''refund'' or ''other remedial action,'' as those terms are used in paragraph 1001.952(g)(7)(ii).

Response: As explained in the preamble to the OIG Proposed Rule, OIG's proposed definition is largely modeled after the definition of ''warranty'' in the Magnuson-Moss Act, codified at 15 U.S.C. 2301(6), which defines ''refund'' as refunding the actual purchase price (less reasonable depreciation based on actual use where permitted by rules of the Commission). Although we have not explicitly adopted this definition, it provides persuasive guidance as to how we would interpret the term ''refund.''

Regardless of how ''refund'' is defined, our proposed safe harbor contemplates that manufacturers or suppliers may ''take other remedial action'' if an item fails to meet the specifications set forth in the written arrangement. It is conceivable that a partial refund or retrospective rebate resulting in a price adjustment would constitute ''other remedial action'' as long as all other conditions of the safe harbor were met.

Comment: Several commenters recommended that OIG expand the list of permissible types of remuneration in paragraph 1001.952(g)(7)(ii) to allow for ''reperformance of services.''

Response: Our definition of ''warranty'' includes an arrangement ''to refund, repair, replace, or take other remedial action. . . .'' If a warranty arrangement is connected to the sale of a bundle of items and services, ''reperformance of services'' likely would be an ''other remedial action'' under the safe harbor as long as all other safe harbor conditions were satisfied, including that the total remuneration provided (in whatever form) cannot exceed the cost of the items and services subject to the bundled warranty arrangement.

Comment: A commenter recommended that in addition to protecting warranty arrangements that provide remuneration in the event of product failure, the safe harbor should allow vendors to receive success payments in the event legitimate value-based objectives are achieved.

Response: The warranties safe harbor is designed to protect warranty arrangements in which vendors offer remuneration to their customers in the event one or more items, or a bundle of one or more items and related services, fails to meet a specified level of performance. The safe harbor does not by its terms protect arrangements in which customers pay success fees to vendors contingent upon achieving certain outcomes. Depending on how such an arrangement is structured, remuneration paid by a customer to a vendor might not implicate the anti-kickback statute, or it might fall within a different safe harbor, such as the revised safe harbor for personal services and management contracts and outcomes-based payment arrangements. Any such arrangements should be reviewed and analyzed under the anti-kickback statute on a case-by-case basis.

Comment: A commenter urged OIG to provide examples of the types of clinical outcomes guarantees that could be protected under the warranties safe harbor. Another commenter expressed concern regarding whether outcomes can properly be guaranteed by suppliers or manufacturers of warrantied items.

Response: As noted above, we believe the expanded warranties safe harbor could be used to protect a wide range of warranty arrangements including, as we discussed in the preamble to the OIG Proposed Rule, warranty arrangements conditioned on clinical outcomes guarantees. In this final rule, we decline to provide specific examples of the types of clinical outcomes guarantees that might be protected because we do not wish to narrow the scope of innovative arrangements that might seek coverage under the safe harbor.

Comment: A commenter asked OIG to clarify that the warranties safe harbor would protect an arrangement in which a warranty payment could vary depending on the product's performance on one or more dimensions specified in the warranty arrangement, as opposed to the warranty payment being a fixed amount.

Response: The warranties safe harbor—both in its existing form and as modified by this final rule—is silent on whether a warranty arrangement protected under the safe harbor can have a single triggering condition or multiple triggering conditions in order to qualify for safe harbor protection. We believe, however, that a warranty arrangement could have multiple triggering conditions based on specifications set forth in the warranty undertaking. In such an arrangement, the seller must still comply with paragraph 1001.952(g)(4) in determining the maximum amount of remuneration it could offer for any given item, bundle of items, or bundle of items or services.

Comment: Some commenters encouraged OIG to make clear that a ''buyer'' as referenced in the safe harbor includes an indirect buyer such as a payor or pharmacy benefit manager. Another commenter asked OIG to coordinate with CMS to recognize that reimbursement for or replenishment of items and services, pursuant to a warranty arrangement, is excludable from price reporting under CMS's government pricing regulations and guidance, including determining how warranty arrangements involving pharmaceutical products and manufacturer-supported adherence programs impact CMS's determination of best price.

Response: The warranties safe harbor does not contain a definition of the term ''buyer,'' and the modifications to the safe harbor that we are finalizing do not affect the scope of individuals and entities that may receive protection under the safe harbor as buyers. Consistent with our approach elsewhere in this final rule, we decline to label certain individuals or entities as ''buyers'' in order to encourage innovation. The commenter's request regarding price reporting under CMS pricing regulations and guidance is outside the scope of this rulemaking.

Comment: A commenter expressed concern that the safe harbor's definition of warranty is not sufficiently broad to protect warranties that guarantee achievement of value-based outcomes.

Response: As modified, the safe harbor protects arrangements that guarantee ''a specified level of performance'' of an item, a bundle of items, or a bundle of items and services. We clarified in the preamble to the OIG Proposed Rule that the warranties safe harbor's protection could extend to arrangements conditioned on clinical outcomes guarantees, which could include warranties conditioned upon ''value-based'' outcomes that meet the safe harbor's other requirements. We believe this offers buyers and sellers significant flexibility to structure arrangements that guarantee achievement of value-based objectives in the context of a warranty. The advisory opinion process remains available for parties seeking OIG's legal opinion on a specific arrangement.

12. Local Transportation (42 CFR 1001.952(bb))

Summary of OIG Proposed Rule: We proposed to modify the existing safe harbor for local transportation at paragraph 1001.952(bb) to: (i) Expand the distance limitations applicable to residents of rural areas from 50 to 75 miles (including for shuttle services); and (ii) remove any mileage limitation for a patient transported from an inpatient facility from which the patient has been discharged after admission as

an inpatient to the patient's residence or another residence of the patient's choice. We indicated that we were considering and solicited comments on whether to eliminate the mileage limitation for patients discharged from certain settings and to extend the safe harbor to protect transportation for nonmedical purposes that may improve or maintain patient health. We provided preamble guidance to clarify that we believe nothing in the language of the safe harbor precludes protection for transportation offered through ride-sharing services and invited commenters to share any basis for disagreement. We also proposed a technical change to move undesignated definitions set forth in the note to paragraph 1001.952(bb) to a new paragraph 1001.952(bb)(3).

Summary of Final Rule: We are finalizing the proposed modifications to the safe harbor at paragraph 1001.952(bb), with modifications. With respect to transportation following an inpatient admission, we clarify that the mileage limits do not apply when the patient is discharged from an inpatient facility following inpatient admission or released from a hospital after being placed in observation status for at least 24 hours. We retain our guidance regarding rideshare programs and do not extend protection under the safe harbor to transportation for non-medical purposes. We finalize the technical reorganization.

a. Expansion of Mileage Limit for Patients Residing in Rural Areas

Comment: Many commenters supported our proposal to increase the mileage limit for safe harbor protection of transportation of residents of rural areas to 75 miles. One such commenter explained that an expansion to 75 miles would meaningfully ''capture'' the communities and patients it serves and enable those patients who live farther away to access specialty services such as cancer care, neurology, transplant, and other specialties that are typically concentrated in larger hospitals located in urban areas. Another commenter stated that because many rural residents must travel more than 50 miles to obtain medically necessary services, increasing the limit to 75 miles likely would improve access to health care for many rural residents.

However, not all commenters agreed. A commenter explained that rural areas are increasingly reporting shutdowns of local health care providers, which increases the distance traveled to receive necessary care. The commenter pointed to examples of closings of nursing homes resulting in patients being moved farther away. The commenter explained that a mileage limitation of 75 miles in rural areas would be insufficient because it is not uncommon for skilled nursing facilities and assisted living facilities to be located 150 miles or more from hospitals, physician's offices, outpatient facilities, and other clinical locations. The commenter advocated for OIG to expand the mileage limitation to 150 miles in rural areas; alternatively, the commenter suggested that OIG expand to 75 miles for all patients and 150 miles for transports originating in a rural area as defined under the U.S. Census Bureau's classification guidelines.

Response: We are finalizing the proposed expansion to 75 miles for residents of rural areas. In the OIG Proposed Rule, we explained that commenters to the OIG RFI stated that the existing local transportation safe harbor's 50-mile limit for rural areas was insufficient because many residents of rural areas needed to travel more than 50 miles to obtain medically necessary services. We proposed to increase the mileage limit for rural areas to 75 miles and solicited comments on whether this increase would be sufficient. We further solicited data and evidence about appropriate distances, as well as information about patients needing transportation and how longer distance transportation would be provided. We indicated that we would use the information to assist us in determining whether an increased distance limit is necessary and practical and whether it is likely to be subject to abuse.

For the following reasons, we have determined that an increase to 75 miles is necessary and practical, and we are finalizing the 75-mile limit. In combination with all of the conditions of the safe harbor, we conclude that the increased mileage limit is not likely to be subject to abuse. Commenters on this topic universally supported an expanded mileage limit for rural areas, and many supported our specific proposal of 75 miles. The final safe harbor will expand safe harbor protection and facilitate access to health care for residents of rural areas, including those seeking types of specialty care often concentrated in urban areas. The expanded mileage limit facilitates access to care for rural area patients whose travel distances have increased due to provider closings.

The existing safe harbor contains a single, uniform mileage limit for rural areas, offering a bright line standard that is practical and clear to administer from a compliance perspective. Our final rule preserves this structure. Accordingly, we are not adopting the suggestion to create a longer distance standard applicable only to transports originating in rural areas. Nor are we adopting the suggestion to extend the mileage limit for rural areas to 150 miles. The safe harbor is intended for local transportation and this limit to local transportation is rooted in the legislative history in connection with the Beneficiary Inducements CMP. In enacting the CMP provision prohibiting inducements to Federal and state health care program beneficiaries, Congress intended that the statute not preclude the provision of complimentary local transportation of nominal value.[136] We are concerned that 150 miles would be neither local nor appropriately address risks of abuse, such as inducing beneficiaries to travel long distances for care when they might prefer and be able to obtain comparable care more locally.

We are mindful of the disruptions and burdens on patients in rural areas when local providers close and patients are transferred or must seek care at more distant locations. The news reports cited by the commenter describe some patients being transferred from closed nursing facilities between 50 and 75 miles away and others moving longer distances. We believe the expanded limit we are finalizing should help many patients facing longer travel distances. We recognize that the safe harbor will not protect every instance of needed transportation. This does not mean that programs offering transportation for rural area patients at greater distances are unlawful. To the contrary, such programs may be lawful depending on their facts and circumstances and would need to be evaluated on a case-by-case basis under the statute, including with respect to the intent of the parties. We remind stakeholders that the OIG advisory opinion process remains available for parties seeking to determine whether a particular arrangement complies with the law. We note that our further modification of the safe harbor to eliminate any distance limit for beneficiaries needing transportation from hospital inpatient or observation stay services to their residences, which can include nursing facilities, will also assist residents in rural areas facing longer travel distances to obtain health care.

Comment: While some commenters found the increase of the limit for transportation of residents of rural communities to 75 miles to be sufficient

[136] H.R. Conf. Rep. No. 104–736 at 255. *See also* 79 FR 59717, 59722–23 (Oct. 3, 2014); 81 FR 88368, 88379 (Dec. 7, 2016).

to address patient needs, many commenters advocated for OIG to expand the mileage limit further for certain categories of patients, such as those patients who live in areas without public transportation, those who have no health care facilities within 75 miles of their home, or those who lack access to specialty health care services due to the closures of nearby rural hospitals. For example, a transportation company shared OIG's desire to expand transportation access in rural areas and explained that 20 percent of Americans live in rural areas but that rural hospital closures have increased significantly in recent years. The commenter suggested that OIG remove the distance limit so that it could provide transportation for rural patients who now have to travel longer distances to receive care. According to the commenter, rural communities face limited transportation options, and reliable transportation could effectively close gaps in access to care.

Commenters suggested various options that generally would tie protection for transportation beyond 75 miles to a patient's medical need. For example, a commenter recommended that we protect transportation that is greater than 75 miles if the eligible entity determines that a patient requires a medical procedure and the nearest provider of such procedure is more than 75 miles from the patient's residence. At least one commenter suggested that we impose additional monitoring requirements when transportation in excess of the proposed mileage limit is necessary.

Another commenter suggested protection for transportation exceeding 75 miles when the provider certifies in writing that there is no alternative provider available within 75 miles of the patient's home and that the transportation is furnished based on patient need using a good faith, individualized determination that the transport is necessary to facilitate the patient's access to medically necessary items or services. However, some commenters expressed concern that requiring a demonstration of need for transportation exceeding 75 miles would unnecessarily complicate the provision of transportation services, could lead to administrative burden, and would not further the objectives of the safe harbor. At least one of these commenters suggested that, if it does impose such a condition, OIG should recognize a range of need assessment tools.

Another commenter suggested that OIG should expand the mileage limitation beyond 75 miles for ''frontier areas'' (which the commenter recommended that we define using selected levels from either commuting codes or frontier and remote codes), but it recommended that we include safeguards to prohibit bypassing locally available health care. At least one commenter asserted that no demonstration of financial, medical, or transportation need should be required for transportation above the current limits because the requirement for transportation to be for medically necessary items or services serves as sufficient protection.

Response: For the reasons in the prior response, we are finalizing our proposal to increase the rural area mileage limit from 50 miles to 75 miles but are not extending it farther. For the reasons that follow, we are not adopting the suggestions to expand safe harbor protection for distances beyond 75 miles in the specific circumstances suggested by commenters (*e.g.,* instances where eligible entities determine or certify that there is a medical need, areas lacking public transportation or access to specialty health care services, or areas where rural hospitals have closed).

We are maintaining the current safe harbor design of a single, uniform mileage limit for rural areas, which offers bright-line guidance and reduces administrative burden, including the administrative burden associated with the need to obtain certifications and/or other evidence of need determinations. We acknowledge and agree with commenters' concerns that imposing a patient need standard for exceptions to the general mileage limitations in the safe harbor could be administratively burdensome, and we are not adopting a patient need standard as a condition of the safe harbor. In the 2016 rule finalizing the local transportation safe harbor, we stated that while we understand that a set mileage limit is not a one-size-fits-all solution, we believe that a bright-line rule is easier for all parties to apply.[137] This remains true. Specifically, the expansion of the mileage limitation combined with the bright-line rule should benefit many patients in rural and underserved areas and should be easy for eligible entities to apply in practice.

Furthermore, if we were to expand the mileage limit for specific types of patient need, we are concerned that providers could develop arbitrary criteria that do not reflect legitimate need and are subject to abuse. We are also concerned that, in many instances, exceptions could swallow the mileage-limitation rule, which we view as a fundamental safeguard and consistent with the safe harbor's intended focus on local transportation.[138] On balance, including additional monitoring or certification conditions would not mitigate these concerns sufficiently to warrant the extra administrative burden.

In finalizing this proposal, we aim to balance the needs of rural patients to have access to quality health care with our concerns that patients could be transported for unnecessary care or be swayed to use a more distant provider even when they may prefer to receive items or services from a local provider. Transportation arrangements in rural areas or to address specific fact patterns such as hospital closures, lack of public transportation, or access to specialty health care services are not necessarily unlawful and would be evaluated for compliance with the statute on a case-by-case basis, including with respect to the intent of the parties. Individuals and entities that participate in value-based enterprises as VBE participants may look to the patient engagement and support safe harbor paragraph 1001.952(hh) as an additional or alternative avenue of protection for certain transportation services. Parties may also use OIG's advisory opinion process for specific facts and circumstances that may fall outside safe harbor protection.

Comment: Some commenters requested wholesale exemption from any mileage limitations under the safe harbor. Several commenters representing Indian health care providers asked that the safe harbor not include any mileage limitations for transportation provided by Indian health care providers; in addition, some of these commenters advocated removing any restrictions regarding the use of Federal funds by Indian health care providers for the cost of transportation furnished to their beneficiaries. Some of these commenters recommended that OIG expand the safe harbor to protect free emergency transportation and air transportation for patients of Indian health care providers.

A commenter that represents community health centers recommended that OIG exempt certain health centers from the mileage limits because Federal regulations issued by the Health Resources and Services Administration require certain health centers to provide transportation services as needed for adequate patient care.[139]

Another commenter suggested that OIG expand the safe harbor for

[137] 81 FR 88388 (Dec. 7, 2016).

[138] 81 FR 88387–89 (Dec. 7, 2016).

[139] 42 U.S.C. 254b(b)(1)(A)(iv).

transportation for homeless individuals in a manner that aligns with California Health and Safety Code section 1265.2(o), which requires documentation that a hospital prior to discharge of a homeless patient has offered the homeless patient transportation to a specified destination if that destination is within a maximum travel time of 30 minutes or a maximum travel distance of 30 miles of the hospital. Numerous commenters suggested that OIG expand the mileage limit for ''special patient populations,'' such as patients undergoing cancer or behavioral health treatment or receiving dialysis services, regardless of whether such patients reside in a rural or urban area. According to these commenters, these special patient populations often need transportation services to care facilities over much greater distances than 25 or 75 miles in order to access quality care to treat their medical conditions. At least one such commenter recommended that OIG require providers to use ''reasonable measures'' (*e.g.,* a shortage of appropriate medical facilities or health care professionals in a geographic area) that would be evaluated based on the totality of the circumstances for each individual.

Response: In developing this final rule, we considered the comments offered by entities that provide services for communities with unique health care needs. The commenters raise important considerations about access to care for Tribal, rural, and underserved communities, an area of ongoing interest for OIG in our work to look at the effectiveness of HHS programs. Here, however, we have concerns regarding the fairness of eliminating the mileage limitation for populations of patients with specific health conditions while imposing mileage restrictions on patients with other health conditions. It would also be difficult to craft a fair and sufficiently bright-line rule allowing for exceptions to the mileage limitation based on ''reasonable measures'' evaluated on a case-by-case basis. Furthermore, any such exception would be difficult to administer.

We note that lack of access to care in a particular geographic area could be a relevant factor in determining on a case-by-case basis whether a particular local transportation arrangement involves an improper inducement to a beneficiary under the Federal anti-kickback statute or Beneficiary Inducements CMP. Depending on the specific facts and circumstances of the arrangement, arrangements could comply with the statutes even if they do not fit in the safe harbor. OIG's advisory opinion process is better suited than the local transportation safe harbor to evaluate arrangements on a case-by-case basis.[140] Moreover, depending on the specific facts of the arrangement, transportation furnished by a VBE participant to patient populations including those identified by the comments summarized above could be structured to qualify for protection under the patient engagement and support safe harbor paragraph 1001.952(hh) that we are finalizing in this rule.

In response to commenters that requested OIG remove any restrictions regarding the use of Federal funds for the cost of transportation furnished to their patients, we did not propose to modify the existing prohibitions on shifting the cost of protected transportation to any Federal health care program, other payors, or individuals, and we are not finalizing any such changes here. The existing prohibition serves important program integrity purposes, as described in the 2016 final rule.[141] In addition, we recognize that other statutes or regulations may govern an entity's provision of transportation to patients and may impact the ability of an entity to structure an arrangement that squarely satisfies the conditions of the local transportation safe harbor.

Where parties are required by Federal or State law to provide transportation services to certain patients or to provide transportation services as part of a service covered by a Federal health care program or other Department program, those arrangements might not implicate the Federal anti-kickback statute. If the patient is entitled to receive services under their Federal health care program coverage, the parties should assess whether there is any remuneration passing to the patient; providing a covered item or service paid for by a Federal health care program alone would not result in an exchange of any remuneration under the Federal anti-kickback statute. However, there could be circumstances under which a provider or supplier, when furnishing a covered item or service, does give a Federal health care program beneficiary something of value, or remuneration, thereby implicating the Federal anti-kickback statute. For example, the Federal anti-kickback statute would be implicated by a provider waiving or reducing any required cost-sharing obligations for the covered item or service incurred by a Federal health care program beneficiary or providing ''extra'' items and services for free that are not part of the covered item or service. Furthermore, we remind stakeholders that an arrangement that does not satisfy all conditions of the local transportation safe harbor does not necessarily violate the Federal anti-kickback statute. The advisory opinion process remains available to stakeholders seeking prospective protection for transportation arrangements that do not fit within the four corners of the safe harbor.

As an initial matter, we note that this safe harbor, as finalized, does not modify existing Federal law regarding IHS appropriations for transportation services furnished to its beneficiaries. While some commenters sought safe harbor protection for air transportation furnished to certain populations, we note that we exclude protection for free or discounted air transportation under the existing local transportation safe harbor and we did not propose changes to this provision. Although we are not adopting this suggestion, we are promulgating clear mileage limits to provide additional flexibilities to stakeholders to benefit all patients, including patients served by Indian health care providers and community health centers. With respect to the comment requesting protection for free emergency transportation, we did not propose changing the safe harbor's restriction on ambulance-level transportation and are not making this change. To the extent free emergency transportation means waiving beneficiary cost-sharing—cost-sharing waivers based on good faith—individualized determinations of the beneficiary's financial need have long been acceptable under OIG guidance.

Comment: A commenter asked OIG to consider protecting transportation to an alternative health care provider without a mileage limitation in the event that one of a provider's locations must divert scheduled patients with urgent needs due to a disaster or similar emergency circumstances.

Response: We are not adopting this recommendation to remove the mileage limitation for the reasons noted above with respect to other commenter suggestions for specific exceptions to the mileage limit based on various types of need. OIG is mindful of the need to protect patients whose availability of care is impacted by natural disasters, public health emergencies, and other exigent circumstances. For example, in response to the COVID–19 public health emergency, OIG has publicly answered inquiries from the health care community regarding the application of

[140] OIG, OIG Adv. Op. Nos. 00–07, 09–01, 15–13, and 16–02. (OIG has issued several favorable advisory opinions in this area.)

[141] 81 FR 88389 (Dec. 7, 2016).

OIG's administrative enforcement authorities under the Federal anti-kickback statute and the Beneficiary Inducements CMP, including to transportation arrangements.[142] It is important to note that the presence of exigent circumstances can be a relevant factor in determining whether the Federal anti-kickback statute would be implicated or violated by a particular transportation arrangement.

Comment: Numerous commenters encouraged OIG to expand the mileage limitation for transportation furnished to patients that reside in urban areas, as defined by the existing safe harbor. A commenter asserted that many Metropolitan Statistical Areas extend beyond 25 miles, and some health care providers in those communities have developed evidenced-based clinical quality intervention strategies for high-risk patients that rely on free patient transportation. At least one commenter suggested that providing urban patients with safe, reliable transportation over a distance greater than 25 miles is a low-cost, high-value way to ensure access to care, and advocated for OIG to expand the mileage limit for urban areas from 25 miles to at least 50 miles. Another commenter urged OIG to add flexibility in instances when the nonrural patient demonstrates a financial, medical, or transportation need.

Response: We did not propose to expand the mileage limits for protected transportation furnished to patients residing in urban areas and, therefore, we are not finalizing any such expansion here.

b. Elimination of Distance Limitations on Transportation of Discharged Patients to Their Residence

Comment: Many commenters strongly supported OIG's proposal to eliminate any distance limit on transportation furnished to a patient who has been discharged from a facility after admission as an inpatient, regardless of whether the patient resides in an urban or rural area, if the transportation is to the patient's residence or another residence of the patient's choice. Numerous commenters recommended that OIG clarify in the final rule that a ''residence'' includes custodial care facilities, including but not limited to nursing facilities, which can serve as a patient's residence on a permanent basis. Another commenter asked OIG to confirm that a patient's residence may include a homeless shelter.

Response: We confirm that we intend for the term ''residence'' as used in paragraph 1001.952(bb)(1)(iv)(B) to include custodial care facilities that may serve as a patient's permanent or long-term residence provided that the patient established the custodial care facility as a residence before receiving treatment by the facility from where the patient is being transported. In addition, we intend the term ''residence'' to include a homeless shelter when a patient is homeless or established the homeless shelter as a residence prior to hospital admission. While not raised by commenters, we also affirm our statement in the OIG Proposed Rule that a residence of the patient's choice can include the residence of a friend or relative who is caring for the patient post-discharge.[143] As long as the other requirements of this safe harbor are met, transportation to these locations would be protected. We also confirm our intention, as noted in the OIG Proposed Rule's preamble and raised in the comment above, that this post-discharge analysis is not dependent on whether the patient resides in a rural or urban setting.[144]

c. Transportation to Locations Other Than a Patient's Residence or a Residence of the Patient's Choice

Comment: Many commenters, including multiple associations representing health care providers, advocated for OIG to modify the safe harbor to protect transportation to any location of the patient's choice, including to another health care facility when there is a medical need for the transfer. Commenters provided various examples of instances when they believe hospitals, other providers, and patients could benefit when patients are transferred to other facilities. For example, some commenters explained that individuals seen in the emergency room may require transportation to another health care facility, while a trade association representing hospitals stated that a patient's medical needs may require being discharged from an inpatient facility directly to post-acute care.

Another commenter expressed concern that, without the ability to provide transportation to another health care facility, skilled nursing facilities may be limited in their ability to transport discharged patients to a hospital, to a hospice, or to other long-term care facilities. Another commenter added that SNF patients often require transportation services following discharge to accommodate any mobility limitations.

Response: After considering the comments, we are not extending safe harbor protection to transportation of patients to any location of their choice or another provider or facility. In developing this final rule, we reviewed and weighed the examples provided by commenters of situations when they believed it would be beneficial for a patient to be transported to another provider following discharge as an inpatient from a facility. We agree that the examples described by the commenters could benefit patients in many circumstances. However, we believe that protecting transportation between health care providers in a position to refer to each other is not sufficiently low risk to warrant safe harbor protection because of the risk that such transportation arrangements could be used to steer patients to health care facilities that may not be in the patients' best interests; for instance, the entity sponsoring the transportation might limit transportation improperly to affiliated facilities to generate system revenue and as a result may interfere with patient choice. Arrangements that do not fit in the safe harbor are not necessarily prohibited under the anti-kickback statute. Under the final rule, patients discharged from inpatient facilities may be offered transportation to a nursing facility if it is their residence.

In this final rule, OIG is finalizing a new safe harbor at paragraph 1001.952(hh) that may protect certain patient engagement tools and supports including transportation when the offeror of the transportation is a VBE participant. As long as all of the safe harbor's conditions are satisfied, the safe harbor at paragraph 1001.952(hh) could protect transportation of patients from an inpatient hospital to another health care facility for post-acute care treatment.

In addition, we emphasize that safe harbors are voluntary and that any assessment of liability under the Federal anti-kickback statute requires an analysis of the facts and circumstances specific to the arrangement, including the intent of the parties. For arrangements that do not meet all requirements of the safe harbor, the party could seek an advisory opinion.

[142] *See* FAQs–Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID–19) Public Health Emergency, *available at https://oig.hhs.gov/coronavirus/authorities-faq.asp* (describing that, under the unique and exigent circumstances resulting from the COVID–19 outbreak, certain modest transportation assistance would present a low risk of fraud and abuse under the Federal anti-kickback statute and the Beneficiary Inducements CMP).

[143] 84 FR 55751 (Oct. 17, 2019).

[144] 84 FR 55751 (Oct. 17, 2019).

d. Elimination of Distance Limitations for Patients Other Than Those Discharged After an Inpatient Admission

Comment: Numerous commenters requested that OIG expand the proposed exemption from distance limitations beyond discharged hospital inpatients to include patients treated in a hospital outpatient department, ambulatory surgery center, or hospital emergency room, as well as patients held in observation status at the hospital for a substantial period of time but who are not admitted. For example, a trade association representing hospitals asserted that patients may travel a significant distance to obtain treatment that does not require an admission, and the commenter believed that transportation home for these patients without a limitation on distance would be appropriate. The commenter suggested that OIG could provide parameters for protected transportation so that it is not used as a workaround to the mileage limitations that otherwise serve as a condition of the safe harbor. To this point, a commenter suggested that an appropriate safeguard to limit potential fraud concerns would be to require a medical justification to receive transportation home for reasons other than an inpatient discharge (*e.g.,* after a colonoscopy or after receiving stitches, a licensed medical professional could determine that a patient is unable to travel home safely).

Response: As finalized in this rule, the mileage limitation of this safe harbor does not apply in two circumstances. First, we confirm our intention, as noted in the OIG Proposed Rule's preamble, that the elimination of the mileage limitation applies after admission as an inpatient. Second, we are persuaded by commenters that we should expand the safe harbor by removing the mileage limitation when a patient is discharged after spending 24 hours in observation status. We indicated in the OIG Proposed Rule that we were considering including transportation for patients who have been under observation status for a timeframe of at least 24 hours. We are including this provision in the final rule because we believe that transportation home following an extended stay in observation status at a hospital is sufficiently similar to transportation home following an inpatient discharge and to prevent any safe harbor compliance challenges resulting from a patient's status as an inpatient or outpatient in the hospital.

We also solicited comments regarding transportation home for patients seen in the emergency department or following a procedure at an ambulatory surgery center. We are mindful that available transportation home for these patients could help address a legitimate need. However, we are not removing the mileage limitation for other patients categorized as outpatients, including patients who are seen in the emergency room but not under observation for at least 24 hours, or patients discharged from an ambulatory surgical center. It is not clear that we could define acceptable medical justifications or make distinctions about categories in this safe harbor. Moreover, creating an exception to the mileage limitations in the safe harbor for local transportation for these categories of patients would make the exception so expansive and overly broad so as to limit the utility of the mileage limitations as safeguards against potentially abusive arrangements. The OIG advisory opinion process remains available for particular transportation programs not covered by this safe harbor.

In promulgating this safe harbor, we observed that Congress did not intend to preclude the provision of local transportation of nominal value in the context of beneficiary inducements. Although the Federal anti-kickback statute has no such exception for remuneration of nominal value, we stated that protection of complimentary local transportation that met certain requirements that limit the risk of fraud and abuse was warranted.[145] We believe that transportation home following inpatient discharge or a stay in observation status at a hospital for at least 24 hours poses a sufficiently low risk of inducing patient referrals to the hospital, provided all safe harbor conditions are met.

e. Local Transportation for Health-Related, Nonmedical Purpose

Comment: Commenters generally supported extending protection under this safe harbor to transportation furnished for nonmedical purposes. For example, some commenters, including trade associations whose members are hospitals or nurse practitioners, encouraged OIG to protect transportation to obtain services that address social determinants of health (*e.g.,* nutrition counseling, chronic disease counseling services, housing services), even if those services do not constitute medical care. The commenters posited that these services have a direct effect on a patient's health outcomes and well-being and are critical to achieving effective care transitions and improved outcomes, including reduced readmissions. One such commenter asked OIG to support hospitals' efforts to connect patients to nonmedical care and foster innovative community collaboration.

Another commenter advocated for protection of transportation to access nutritious foods, suggesting that patients living in a ''food desert'' may have difficulties obtaining such foods, which the commenter asserted could potentially lead to increased health care costs later if the patients develop nutritional issues that require medical attention. A commenter also suggested that transportation to food stores, food banks, other non-health care social services (*e.g.,* housing assistance), or agencies that offer employment or vocational training would be appropriate for safe harbor protection. A commenter asked OIG to clarify the types of non-medical purposes that OIG believes should not be protected by any expansion of the safe harbor.

Some commenters suggested potential safeguards for expanded safe harbor protection for transportation for non-medical purposes. Recognizing the need to minimize the risk of fraud and abuse that may arise in conjunction with non-medical transportation, such as inducing beneficiaries to receive unnecessary health care items and services, these commenters suggested a variety of safeguards such as: (i) Imposing restrictions on an entity's ability to condition receipt of non-medical transportation support on continued receipt of health care services from a particular provider; (ii) requiring the entity to utilize an independent transportation vendor to arrange for transportation; (iii) requiring the entity to tie any transportation service to a specific quality improvement, social determinant of health, or public health initiative; (iv) requiring that the transportation is unlikely to interfere with, or skew, clinical decision-making; and (v) requiring providers to document the patient's need for such non-medical transportation (*e.g.,* patient's income, medical condition).

Another commenter suggested the existing conditions of the safe harbor, combined with an appropriately tailored scope of nonmedical transportation purposes (*e.g.,* a direct connection to the coordination and management of care), would be a sufficient safeguard against abusive transportation initiatives.

Response: We are not expanding the local transportation safe harbor to protect patient transportation for nonmedical purposes. In response to the OIG RFI, we received comments suggesting that transportation for nonmedical purposes may improve

[145] 81 FR 88379 (Dec. 7, 2016).

patient health, and we solicited comments on whether the safe harbor could be expanded to protect transportation for these purposes without creating an unacceptable risk of fraud and abuse, such as inducing beneficiaries to receive unnecessary health care items and services. Some commenters suggested potential safeguards (*e.g.,* requiring the entity to tie any transportation service to a specific quality improvement, social determinant of health, or public health initiative). While we do not doubt that properly structured transportation for non-medical needs can help patients maintain or improve their health, we believe that protecting transportation for non-medical purposes under paragraph 1001.952(hh), which limits protection of transportation to tools and supports furnished by VBE participants, rather than under the safe harbor for local transportation, presents the lowest risk approach to protecting patients and Federal health care programs from fraudulent and abusive transportation schemes.

We continue to believe that the risk of beneficiaries being improperly induced to obtain items or services is too high for safe harbor protection when the transportation is for non-medical purposes. As we explained in the 2016 final rule establishing the local transportation safe harbor, a transportation program offered by a provider or supplier inherently poses a risk both of inducing patients to get items or services that they might otherwise not have obtained and to get services from that provider or supplier. In the case of transportation for medically necessary items and services, we think that risk is acceptable. However, we believe the risk is too high when the transportation is for non-health-related purposes.[146] We noted that it would be difficult to determine whether non-medical transportation is related to the patient's health care (*e.g.,* transportation to a shopping center that includes both a grocery store and a movie theater). We went on to say that transportation for nonmedical purposes very well might be more frequent than transportation for medical appointments, which would give larger providers a significant competitive advantage over smaller entities or individual suppliers.[147] We explained that transportation for nonmedical purposes would not violate the statute if it is not for the purpose of inducing individuals to obtain federally reimbursable items and services.

Notwithstanding the foregoing, we are mindful of the importance of addressing social determinants of health, and for this reason among others we are finalizing a new safe harbor at paragraph 1001.952(hh) that protects nonmedical transportation offered by VBE participants if such transportation has a direct connection to the coordination and management of care of the target patient population and meets the other conditions of the safe harbor. In promulgating paragraph 1001.952(hh), we recognize that transportation to address social determinants of health could improve patients' overall health and reduce health care costs. However, without the safeguards embedded within the VBE framework, including accountability for advancing value-based purposes, we are concerned that transportation for non-medical purposes could be used improperly to recruit patients or incentivize overutilization of items or services; therefore, OIG is not extending the local transportation safe harbor to include transportation for nonmedical purposes.

f. Use of Ride-Sharing Services

Comment: Commenters supported OIG's clarification in the OIG Proposed Rule that transportation furnished through ride-sharing services could be protected by the safe harbor and that, for purposes of this safe harbor, there is no difference between taxis and ride-sharing services. A commenter emphasized the importance of these services with respect to patients with driving restrictions, cognitive impairments, and mobility limitations. While some commenters did not believe a change to the regulatory text was needed, at least one commenter recommended that we amend the safe harbor to protect transportation via ride-sharing services explicitly; according to this commenter, the safe harbor is ambiguous with respect to ride-sharing services, which discourages some providers from entering into arrangements with ride-sharing services.

A commenter recommended that OIG clarify whether a ride-share service can advertise a partnership with a hospital or health system to promote patient awareness and utilization of such services. Another commenter urged OIG not to make providers responsible for knowing or controlling the advertising practices of taxi companies, ride-sharing services, or other transportation providers.

Response: We support the use of ride-sharing services or other patient transportation services similar to a taxi service by eligible entities to make local transportation available for their patients. The safe harbor protects certain free or discounted local transportation made available by an eligible entity, and we confirm that an eligible entity may make such transportation available through ride-sharing arrangements or through other means of local transportation that may exist in the future (*e.g.,* self-driving cars). We do not believe an amendment to the regulatory text is necessary. Indeed, nothing in the language of the safe harbor prevents the use of ride-sharing services by eligible entities as long as all other conditions of the safe harbor are met. As we explained in the OIG Proposed Rule, although we do not explicitly refer to ride-sharing services within the safe harbor, we see no meaningful differences between these services and taxis, or other similar technology that serve as a taxi service should they become available in the future.[148] We are not explicitly including specific transportation methods within the regulatory text to avoid being overly proscriptive and to allow eligible entities sufficient flexibility to outsource these services appropriately while satisfying every condition of the safe harbor.

We note that eligible entities that make transportation services available to patients by using ride-sharing or other similar transportation service providers must meet all requirements of the safe harbor and ensure such service providers also meet all requirements of the safe harbor to receive protection, including for example the prohibitions against luxury transportation and publicly marketing or advertising the free or discounted local transportation services.

In the OIG Proposed Rule, we explained that a taxi company, ride-sharing service, or other provider of transportation could advertise that it provides transportation to medical appointments and suggest to patients that they contact their medical providers to determine whether free or discounted transportation is available to their facilities. We stated, however, that it cannot advertise that it provides free or discounted transportation to a particular health care provider or group of providers because such customer-specific advertising is within the control of the customer (*i.e.,* the eligible entity paying for the transportation) to prohibit, and therefore would be imputed to the customer and would disqualify transportation furnished by

[146] 81 FR 88384 (Dec. 7, 2016).

[147] 81 FR 88384 (Dec. 7, 2016).

[148] 84 FR 55752 (Oct. 17, 2019).

the customer from safe harbor protection.[149] Accordingly, we strongly suggest that eligible entities that furnish local transportation to patients and choose to rely on this safe harbor have mechanisms in place to ensure this condition of the safe harbor is satisfied.

13. Accountable Care Organization (ACO) Beneficiary Incentive Program (42 CFR 1001.952(kk))

Summary of OIG Proposed Rule: We proposed at proposed paragraph 1001.952(kk) to codify the statutory exception to the definition of ''remuneration'' at section 1128B(b)(3)(K) of the Act, as added under section 50341 of the Budget Act of 2018, for ACOs operating a CMS-approved beneficiary incentive program under the Medicare Shared Savings Program, as defined under section 1899(m) of the Act. We proposed to clarify that an ACO may furnish incentive payments only to assigned beneficiaries and to interpret the statutory language in the Budget Act of 2018 stating, ''if the payment is made in accordance with the requirements of such subsection [section 1899(m) of the Act],'' to mean ''if the incentive payment is made in accordance with the requirements found in such subsection.'' We did not propose any additional safe harbor conditions that incentive payments made by an ACO to an assigned beneficiary under an ACO Beneficiary Incentive Program established under section 1899(m) of the Act would have to satisfy, and we solicited comments on the proposed lack of additional conditions.

Summary of Final Rule: We are finalizing the safe harbor without modifications.

Comment: Several commenters expressed support for the ACO Beneficiary Incentive Program safe harbor. For example, a commenter posited that incentivizing patients to attend primary care appointments may improve patient outcomes and reduce downstream medical expenses. Another commenter agreed with OIG's proposal not to establish additional safe harbor conditions to protect incentives under an ACO Beneficiary Incentive Program that satisfies the statutory exception and regulatory requirements.

Response: We are finalizing the regulation text as proposed. We note that we do not interpret the statutory exception found at section 1128B(b)(3)(K) of the Act, nor the safe harbor finalized at paragraph 1001.952(kk), to require satisfaction of any requirements found outside section 1899(m) of the Act (*e.g.,* the regulatory requirements established by CMS implementing the ACO Beneficiary Incentive Program found at 42 CFR 425.304(c)).

Comment: A commenter supported the codification of the ACO Beneficiary Incentive Program exception in a safe harbor but recommended that OIG broaden the exception to protect any future beneficiary incentives covered under CMS-sponsored payment models and beneficiary incentive options that may be available in the future. According to the commenter, the ACO Beneficiary Incentive Program is too limited and the commenter has advised CMS that ACOs, and alternative payment models (APM) more broadly, should be able to provide beneficiary incentives to subsets of their population. Another commenter requested that OIG expand the safe harbor to protect ACOs participating in any Innovation Center demonstration, noting that several ACO demonstrations have risk-bearing standards that exceed those in the Medicare Shared Savings Program.

Response: This safe harbor codifies a statutory safe harbor that is specific to ACO Beneficiary Incentive Programs; the commenters' suggestions are beyond the scope of the statute and our proposal. To the extent the commenters are requesting safe harbor protection for beneficiary incentives provided through existing CMS-sponsored models developed pursuant to section 1115A(d)(1) of the Act, any fraud and abuse waiver applicable to beneficiary incentives under the relevant model would potentially provide protection as long as the beneficiary incentive arrangement squarely satisfies the conditions of the applicable waiver. Moreover, we are finalizing a new safe harbor for CMS-sponsored models at paragraph 1001.952(ii) that protects certain CMS-sponsored model patient incentives under models for which CMS has determined that paragraph 1001.952(ii)(2) should apply. This new safe harbor is described more fully in section III.B.7 of this preamble.

Comment: A trade association representing community pharmacists recommended that pharmacists be included in the definition of an ''ACO professional'' and that pharmacy services should constitute qualifying services for purposes of the ACO Beneficiary Incentive Program safe harbor. According to the commenter, including pharmacy services as qualifying services would give pharmacists more resources to provide medication adherence services more efficiently to further enhance care coordination.

Response: The commenter's suggestion is beyond the scope of the ACO Beneficiary Incentive Program statutory exception found at section 1128B(b)(3)(K) of the Act that OIG proposed to codify at paragraph 1001.952(kk). Section 1899(h) of the Act defines an ACO professional for purposes of the Medicare Shared Savings Program, and section 1899(m) of the Act sets forth the scope of qualifying services. CMS administers the Medicare Shared Savings Program on behalf of the Secretary, which includes promulgating regulations interpreting the statutory definition of ACO professional and the scope of qualifying services; for this reason, any requests to expand these terms should be directed to CMS.

Comment: A commenter supported the proposed safe harbor but recommended that OIG consider the administrative burden associated with the ACO Beneficiary Incentive Program. In particular, the commenter noted that several requirements of the ACO Beneficiary Incentive Program (*e.g.,* recordkeeping requirements) are burdensome.

Response: The commenter's suggestion is beyond the scope of this rulemaking. Section 1899(m) of the Act contains certain programmatic reporting and documentation requirements for beneficiary incentives under the Medicare Shared Savings Program, and CMS has promulgated additional regulations implementing the ACO Beneficiary Incentive Program.[150] The new safe harbor at paragraph 1001.952(kk) does not alter existing documentation requirements or impose any additional documentation requirements. Furthermore, section 50341(b) of the Budget Act of 2018 does not give OIG authority to waive programmatic documentation requirements set forth in section 1899(m) of the Act or in CMS regulations.

Comment: A commenter requested additional guidance on the specifics of the protected remuneration under this safe harbor.

Response: The new safe harbor at paragraph 1001.952(kk) protects incentive payments made by an ACO to an assigned beneficiary under a beneficiary incentive program established under section 1899(m) of the Act if the incentive payment is made in accordance with the requirements found in section 1899(m) of the Act. We interpret the statutory language in the

[149] 84 FR 55752 (Oct. 17, 2019).

[150] 42 CFR 425.304(c)(4)(i).

Budget Act of 2018 stating, ''if the payment is made in accordance with the requirements of such subsection [section 1899(m) of the Act]'' to mean ''if the incentive payment is made in accordance with the requirements found in such subsection.''

We read this provision broadly to incorporate all the requirements found in section 1899(m) of the Act as requirements of the ACO Beneficiary Incentive Program statutory exception to the definition of ''remuneration'' under the Federal anti-kickback statute. In other words, as we stated in the preamble to the OIG Proposed Rule, we interpret this statutory requirement to mean that for an incentive payment to satisfy the ACO Beneficiary Incentive Program statutory exception, and the corresponding safe harbor interpreting the statutory exception, all of the requirements enumerated at section 1899(m) of the Act—related both to ACO Beneficiary Incentive Programs and incentive payments made pursuant to such programs—must be satisfied. We do not interpret the statutory exception at section 1128B(b)(3)(K) of the Act to require satisfaction of any requirements found outside of section 1899(m) of the Act. For instance, CMS, which administers the Medicare Shared Savings Program, has promulgated programmatic regulations setting forth more detailed requirements for implementing an ACO Beneficiary Incentive Program in accordance with section 1899(m) of the Act. While compliance with these regulations is not a condition of satisfying the safe harbor, it would be prudent for ACOs to review these regulations to ensure that their ACO Beneficiary Incentive Programs meet all applicable programmatic requirements.

C. Civil Monetary Penalty Authorities: Beneficiary Inducements CMP

1. Exception for Telehealth Technologies for In-Home Dialysis (42 CFR 1003.110)

Summary of OIG Proposed Rule: We proposed to amend the definition of ''remuneration'' under the Beneficiary Inducements CMP by codifying the statutory exception enacted as part of the Budget Act of 2018. Specifically, we proposed to add an exception to the definition of ''remuneration'' in paragraph 1003.110 at proposed paragraph 1001.110(10) for the provision of certain telehealth technologies related to in-home dialysis services. The proposed exception would protect the provision of telehealth technologies by a provider of services or renal dialysis facility to an individual with end-stage renal disease (ESRD) who is receiving home dialysis paid for by Medicare Part B, provided the donation meets conditions proposed in the OIG Proposed Rule. We proposed a condition that would require uniform provision of technology. In addition, we proposed to define ''telehealth technologies'' as multimedia communications equipment that includes at a minimum audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner used in the diagnosis, intervention, or ongoing care management—paid for by Medicare Part B—between a patient and the remote healthcare provider.

Summary of Final Rule: We are finalizing this provision with several modifications at paragraph 1003.110(10) to align with the statutory exception in 1128A(i)(6)(J). As explained in more detail below, we are removing most of the additional proposed conditions and proposed regulatory text language that were not in the statutory exception. Additionally, the final rule modifies the definition of ''telehealth technologies'' and includes physicians as a type of practitioner that can donate telehealth technologies to a patient. We are not finalizing the other proposed conditions on which we solicited comments.

a. General Comments

Comment: Commenters on this topic overwhelmingly supported our proposed exception, in many cases as proposed. For example, a commenter stated that the exception would enhance access to telehealth services for vulnerable patients, including those who are immobile or located in rural areas, and would encourage patients to appropriately address their chronic condition. Commenters observed that telehealth technologies will provide an important tool for dialysis facilities and other providers to ease patients' adoption of home dialysis as their treatment modality of choice and that increased use of telehealth services benefit patients, including through reduced travel to and from physician visits. A commenter expressed that broad protection under the Beneficiary Inducements CMP would be consistent with policy priorities of Congress and the Department, as well as under the Executive Order entitled ''Advancing American Kidney Health.'' Another commenter noted the Administration's policy goal of increased rates of uptake and retention of in-home dialysis and urged OIG to consider the impact technologies have outside of an isolated clinical visit, such as dialysis modality education and support group access.

Some commenters raised concerns about the need for safeguards against risks such as inappropriate steering, lemon-dropping, and cherry-picking of patients by providers and the use of free at-home technologies to entice patients to use a particular provider, especially when the technology could also be used for other purposes beyond the provision of telehealth services. Some commenters urged us to adopt the statutory exception without any additional conditions that could create barriers to patients accessing telehealth services, more administrative burden, or additional duties on staff. A commenter stated that the additional conditions and other potential safeguards in the OIG Proposed Rule preamble are unnecessary.

Response: We have made several modifications to the final exception that address the commenters' general concerns. Consistent with the statutory exception at section 1128A(i)(6)(J) of the Act and the OIG Proposed Rule, these modifications finalize a broader definition of ''telehealth technologies,'' reduce the number of conditions from the OIG Proposed Rule, and modify the proposed conditions to more closely align to the statute. The final exception incorporates the statutory text from section 1128A(i)(6)(J) and the two statutory conditions at 1128A(i)(6)(J)(i) and (ii). We describe the specific rationale for each of these modifications in greater detail below.

These modifications reflect our understanding as stated in the OIG Proposed Rule that this is a narrow exception to the CMP beneficiary inducement statute. Primarily, the exception is limited to a subset of patients receiving in-home dialysis and certain, enumerated providers in the statutory exception.[151] Because the exception finalized here is only available to established patients who are receiving specific services paid for by Medicare Part B, the potential for fraud and abuse is reduced. Similar to our rationale related to the definition and use of target patient population in the patient engagement and support safe harbor at paragraph 1001.952(hh), we believe that remuneration connected to an objectively defined set of patients decreases the risk that valuable remuneration will be offered to patients as an inducement to seek care or as a reward for receiving care. For the purposes of this exception, Congress established the patient population as

[151] 84 FR 55754 (Oct. 17, 2019).

those receiving in-home dialysis paid for by Medicare Part B.

Additionally, the two statutory conditions address common risks of fraud and abuse associated with remuneration furnished to beneficiaries. The first, which bars telehealth technologies from being offered as part of any advertisement or solicitation, protects against improper marketing schemes that entice beneficiaries to receive unnecessary services or select providers or services based on promises of valuable gifts rather than medical best interests. The second statutory condition requires that the telehealth technologies are provided for the purpose of furnishing telehealth services related to the recipient's ESRD; this condition tailors the statutory protection to arrangements that assist beneficiaries in managing their ESRD, reducing risk that the provision of telehealth technologies induce orders or purchases of other, unrelated items and services. These statutory limitations reduce the risks of fraud and abuse associated with providing certain beneficiaries with free telehealth technologies.

We share commenters' concerns that offering valuable technology for free to patients has the potential to impact a patient's selection of a provider, and we agree that this exception should not be used to effectuate inappropriate steering, lemon-dropping, or cherry-picking of patients. The risk of fraud and abuse associated with selectively deciding which patients receive telehealth technologies is mitigated by conditions finalized in this rule (*e.g.,* telehealth technologies are protected if provided to a beneficiary already receiving in-home dialysis paid for by Medicare Part B and if that patient initiated contact or scheduled an appointment with the donor (paragraphs (10)(i) and (ii) in 42 CFR 1003.110)).

This final rule strives to foster the policy goal of: (i) Ensuring that beneficiaries can choose and benefit from medically appropriate in-home dialysis care, as determined by the beneficiary and their provider, physician, or renal dialysis facility; (ii) protecting beneficiaries against coercive marketing schemes that do not serve their best interests; and (iii) ensuring that providers, physicians, and renal dialysis facilities are seeking the protection of the exception use telehealth technologies for purposes related to beneficiaries' ESRD as contemplated in the statutory exception. We have endeavored to reduce administrative and staff burden wherever possible, consistent with these goals.

b. Definition of ''Telehealth Technologies''

Summary of OIG Proposed Rule: Using the definition of ''interactive telecommunications system'' pursuant to 42 CFR 410.78(a)(3) as a basis,[152] we proposed to define ''telehealth technologies'' as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner used in the diagnosis, intervention, or ongoing care management—paid for by Medicare Part B—between a patient and the remote healthcare provider. We proposed to exclude telephones, facsimile machines, and electronic mail systems from the definition. However, we proposed that smartphones with two-way, real-time interactive communication through secure video conferencing applications would not be considered ''telephones.'' We sought comments on this definition and whether ''telehealth technologies'' should include technologies such as software, a webcam, data plan, or broadband internet access that facilitates the telehealth encounter.

Summary of Final Rule: We are finalizing, with modifications, the regulatory text defining ''telehealth technologies'' in response to comments and in a way that is technology agnostic, as described further below.

Comment: Several commenters agreed with our proposed definition of ''telehealth technologies'' based on 42 CFR 410.78(a)(3), including our proposal to exclude smartphones from our interpretation of what consists of a ''telephone'' for the purposes of our proposed ''telehealth technologies'' definition because it would help expand access to medically necessary care. A commenter suggested OIG finalize a technology-neutral definition of ''telehealth technologies'' and urged us not to detail specific technologies or services, which are likely to change over time to facilitate the development of more efficient means of delivering the same services. While a commenter agreed with excluding telephones, facsimile machines, and electronic mail systems from the definition of ''telehealth technologies'' because the commenter did not view them as providing the required services, other commenters asserted that these technologies should not be included. For example, a commenter explained that these technologies do not constitute ''telehealth technologies'' as standalone items but can be used to supplement a telehealth encounter.

Several commenters were supportive of including the broader range of technologies considered in the OIG Proposed Rule (*e.g.,* software and data plans). Commenters suggested that these technologies, which alone will not facilitate a telehealth encounter, may be required by some patients to access telehealth services. A commenter asserted that the exception should protect any type of technology as long as it contributes to accomplishing the telehealth service. The commenter also urged OIG to consider that software protected under the exception must be easily downloadable, be easy to use for patients, and meet HIPAA standards.

Another commenter supported narrowly defining ''telehealth technologies'' as the ''interactive communications system'' necessary for the telehealth service. According to the commenter, a broader definition could inappropriately induce a beneficiary to consider in-home dialysis because of the availability of technology benefits rather than the clinical appropriateness of the treatment approach. A commenter also suggested that if necessary we include a list of items ineligible for protection under this exception.

Response: We agree with those commenters that recommended a broader definition that includes items and services that facilitate telehealth services because the goal of this exception, as explained in the OIG Proposed Rule, is to protect a wide range of technologies to better support in-home dialysis. Specifically, this final rule modifies the definition of ''telehealth technologies'' by removing references to specific types of technology, limits on the type of communication, and a requirement that telehealth services be paid for by Medicare Part B. We are revising language to clarify that the definition means technology used to support

[152] In response to the COVID–19, HHS and CMS have exercised emergency authorities and regulatory flexibilities to help health care providers respond to the COVID–19 public health emergency. Specific to telehealth covered by Medicare Part B, CMS has expanded the types of technology that can be used to provide telehealth services, the types of services that can be provided via telehealth, certain coverage requirements related to originating and distant sites, and other flexibilities. Most of these flexibilities will remain in place until the Secretary ends the declaration of a public health emergency for COVID–19. *See for example* 85 FR 19230 (Apr. 6, 2020), COVID–19 Emergency Declaration Blanket Waivers for Health Care Providers, *available at https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf*; 85 FR 27550 (May 8, 2020), Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program, *available at https://www.govinfo.gov/content/pkg/FR-2020-05-08/pdf/2020-09608.pdf.*

communication between providers and patients in instances when the communication is distant or remote, and when the communication is for diagnosis, intervention, or ongoing care management. For purposes of the telehealth technologies exception to the definition of ''remuneration'' authorized under section 1128A(i)(6)(J) of the Act, this final rule defines ''telehealth technologies'' to mean hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for the diagnosis, intervention, or ongoing care management. We note that the revised definition includes all of the technologies that we proposed would constitute telehealth technologies and be protected if all conditions of the exception were met: that is, multimedia communications equipment, including audio and video equipment permitting two-way, real-time interactive communication with the patient.

The revised definition also now includes technologies that we proposed to specifically exclude from the definition: Telephones, facsimile machines, and electronic mail systems. The final definition is technology agnostic. We emphasize that the revised definition retains the element that the technology supports provider and patient communication for diagnosis, intervention, or ongoing care management. Additionally, for a donation of technology to be protected it must meet all conditions of this exception, not just satisfy the revised definition of ''telehealth technologies.'' This includes the condition at paragraph (10)(i) in 42 CFR 1003.110 that requires the telehealth technology be provided for the purpose of furnishing telehealth services related to the recipient's end-stage renal disease. If a provider, physician, or facility determines that a fax machine meets this condition and the revised definition (and the donation meets all other conditions) then it would be protected by this exception.

This modification is consistent with the statutory exception and our solicitation of comments in the proposed rule. In the OIG Proposed Rule, we proposed to define ''telehealth technologies'' to encompass ''multimedia communications equipment'' that included at a minimum audio and video equipment with distant site, interactive communications functionality between patients and physicians or practitioners. We considered whether to broaden the definition to include technology such as software, webcams, data plans, and broadband internet access that facilitate a telehealth encounter and solicited specific comments on the treatment of telephones, facsimile machines, and electronic mail systems.

We are modifying the definition to focus on the functionality of the technology to support telehealth rather than specific types. The revised definition is technology neutral to provide flexibility to providers, physicians, and renal dialysis facilities to determine what telehealth technology is needed for the purpose of furnishing telehealth services related to an individual's ERSD. By ''technology agnostic,'' we mean that the technology is not limited to specific technologies or services, which are likely to change over time. For telehealth and virtual care specifically, we believe a technology-agnostic approach is especially important given, for example, the widespread and rapid changes to telehealth during the response to the COVID–19 public health emergency. This approach will also allow the exception to continue to be available to support telehealth services for ESRD beneficiaries as technology evolves. We recognize that the revised definition will allow for a wider range of technology to be provided to beneficiaries than the proposed regulatory text. We also recognize the potential for ''telehealth technologies'' as defined more broadly in this final rule to inappropriately induce patients to pursue in-home dialysis over a dialysis facility or select a particular provider or physician. However, we believe the risk is mitigated because the exception is available for a defined set of patients already receiving in-home dialysis, marketing is not allowed, and other conditions provide safeguards against fraud and abuse.

The revised definition is supported by the statutory exception in section 1128A(i)(6)(J) of the Act. The statute gives the Secretary authority to define ''telehealth technologies'' and protects technologies provided for the purpose of furnishing telehealth services related to the individual's ESRD. The statute did not limit the telehealth technology or technology services under the exception to any related Medicare definitions. In contrast, section 1128A(i)(6)(J) of the Act states that a provider of services or a renal dialysis facility are defined as those terms are used in title XVIII (Medicare). ''Telehealth technologies'' in section 1128A(i)(6)(J) and the term ''telehealth services'' in 1128A(i)(6)(J)(ii) do not include a reference to specific statutory or regulatory definitions. Therefore, the statute provides the Secretary additional flexibility to interpret these terms differently than any related Medicare definitions. We similarly interpret the term ''telehealth services'' differently than the scope of telehealth services paid for by Medicare Part B. For a more detailed discussion of the term ''telehealth services'' used in paragraph (10)(ii) in 42 CFR 1003.110, see section III.C.1.e below.

Based on the statutory exception and flexibility afforded by the statutory exception and the response to our solicitation on the appropriate scope of technology covered by this exception, we are modifying the definition in the regulatory text of ''telehealth technologies'' to focus on core functionality to support telehealth services and be technology agnostic. As several commenters noted, telehealth technologies are ineffective without the ability to connect any device facilitating telehealth services, and the purpose of this exception would not be advanced without those capabilities. We agree and have expanded the definition of telehealth technologies to include services that support distant or remote communication between the patient, provider, or renal dialysis facility for diagnosis, intervention, or ongoing care management. For example, the finalized definition would include internet service or data plans.

We emphasize that although this definition would encompass various technologies, to receive protection under the exception arrangements for providing telehealth technologies to beneficiaries must squarely satisfy the other conditions in the exception, including that the technologies are provided for the purpose of furnishing telehealth services related to the recipient's ESRD.

In this preamble we offer examples of technology we view as within the scope of the final definition of ''telehealth technologies.'' We are not providing an exhaustive list in regulatory text or preamble to avoid inadvertently limiting telehealth technologies that donors determine are best suited to facilitate telehealth services to beneficiaries with ESRD and to allow for the evolution of technology. We are not including a condition related to ease of use for telehealth technologies furnished to patients, which we believe is a consideration for the patient and the clinician and is not needed as a fraud and abuse safeguard. Parties would need to comply with any other applicable government regulations that address ease of use or functioning of telehealth technology. Similarly, HIPAA and other Federal and State privacy and security laws apply notwithstanding this exception; therefore, we do not believe

an additional condition within this exception is necessary.

Comment: Several commenters asserted that limiting ''telehealth technologies'' to two-way, real-time interactive communications equipment is overly narrow and could bar protection of many beneficial technologies that pose no greater risk than technologies included in the proposed definition. As an example, some commenters suggested that equipment used to monitor and report data to physicians and dialysis facilities (*e.g.,* Bluetooth-enabled stethoscopes and thermometers) would not qualify under the proposed definition but could provide valuable clinical benefits. A commenter suggested that OIG follow the example provided in the current Kidney Care Choices Model operated by the Innovation Center that allows the use of asynchronous store-and-forward technologies and the forwarding of health history to a clinician for review outside of a real-time interaction. Several commenters recommended including real-time (synchronous) and store-and-forward (asynchronous) audio and video platforms. A commenter stated that an audio-only platform may be appropriate to assess whether the patient's condition necessitates an office visit.

Response: We agree with commenters who suggest revising the definition to include broader forms of technology, including technologies that enable asynchronous communications between the patient and a distant site physician or practitioner. We have revised the definition of ''telehealth technologies'' to cover a more expansive range of technology than the proposed definition. This modification to the definition would cover technology based on its function, rather than specific types of technology. This would include equipment that could be used to monitor and report data to physicians and dialysis facilities (*e.g.,* Bluetooth-enabled stethoscopes and thermometers) where appropriate, provided such technologies satisfy the other conditions of the exception. We believe the donor of any protected telehealth technologies—who per the terms of the exception must be currently providing the in-home dialysis, telehealth services, or other ESRD care to the patient—is in the best position to determine whether real-time or asynchronous information is appropriate and whether such technologies serve the purpose of furnishing telehealth services related to the recipient's ESRD. We do not believe the distinction between two-way, real-time technology and asynchronous technology materially changes the fraud and abuse analysis associated with providing patients valuable technology. Relatedly, we agree that some audio-only technology may be appropriate to assess whether the patient's condition necessitates an office visit and could contribute substantially to the provision of telehealth services to a patient.

As explained above, the definition of ''telehealth technologies'' set forth in this final rule is technology agnostic and is not limited, for example, to technologies used for two-way, real-time interactive communication. We believe this final definition will extend protection to many of the specific technologies identified by commenters as long as other conditions of the exception are met.

Comment: A commenter encouraged OIG to define the minimum set of capabilities required for a telehealth physician visit to include at least real-time bidirectional video interaction with audio. The commenter recommended the definition for ''telehealth technologies'' include tools such as peripheral devices or applications that the physician deems necessary to complete a proper assessment of the patient during a telehealth service, including remote monitoring and asynchronous messaging.

Another commenter recommended OIG adopt the full definition of ''interactive telehealth system'' at 42 CFR 410.78 in lieu of the proposed ''telehealth technologies'' definition but expand the definition to protect the use of asynchronous technologies in certain geographic areas (*e.g.,* areas that are medically underserved). The same commenter also recommended including peripheral or supporting technology in the definition, which could support the use of remote patient monitoring.

Response: As described above, we have modified the definition of ''telehealth technologies'' to clarify the scope of technologies with telehealth capabilities protected by this exception. With respect to real-time bidirectional video interaction with audio, we view such technology as within the scope of the proposed definition as well as the definition finalized here. We also agree with the commenter that the definition should include tools such as peripheral devices or applications that the physician deems necessary to complete a proper assessment of the patient during a telehealth service. The definition of ''telehealth technologies'' encompasses the peripheral or supporting technologies for remote patient monitoring noted by the commenter. Asynchronous technologies would also meet the definition of telehealth technologies and could be protected if all conditions of the exception are met. For example, many types of remote patient monitoring technology are asynchronous and used to support remote communication between a patient and their physician for diagnosis, intervention, and ongoing care management. We did not propose and are not adopting any geographic limitation. Such restrictions are not necessary due to the other safeguards in the safe harbor, and further narrowing the limited statutory exception is not consistent with the statutory text (*e.g.,* section 1128A(i)(6)(J) of the Act is not connected to telehealth services paid for by Medicare Part B, which are historically subject to geographic limitations).

We note that policies regarding what constitutes a physician telehealth service are outside the scope of this rulemaking because it is limited to requirements for an exception to the Beneficiary Inducements CMP.

Comment: Another commenter recommended aligning the exception with the list of services payable under the Medicare Physician Fee Schedule when furnished via telehealth by expanding the definition of ''telehealth technologies'' to include communications-based technologies in addition to telehealth technologies.

Response: We believe the commenter is referring to the telehealth technologies used to furnish ''communications technology-based services'' such as virtual check-in and remote assessment services that are separately billable under Medicare Part B. As discussed above, we have revised the definition of ''telehealth technologies,'' and it would include technologies that facilitate communications for these services including, by way of example, virtual check-in services. This exception protects a wide range of telehealth technologies that are provided for the purposes of furnishing remote or distant services through various modalities, including telehealth services, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring.

Consistent with this approach, as explained more fully above, we have modified the telehealth technologies definition so that it is not dependent on Medicare Part B payment for telehealth services. Relatedly, as explained more fully below, we are also modifying paragraph 10(iii) under the definition of ''remuneration'' in 42 CFR 1003.110 so that protection of telehealth

technologies is not conditioned on their being provided for the purpose of furnishing ''telehealth services'' paid for by Medicare Part B.

c. Furnished by Specified Individuals and Entities Currently Providing Care to the Patient

Summary of OIG Proposed Rule: Section 1128A(i)(6)(J) of the Act limits the exception to technologies provided ''by a provider of services or a renal dialysis facility (as such terms are defined for purposes of title XVIII) to an individual with end-stage renal disease who is receiving home dialysis for which payment is being made under part B of such title . . . .'' We proposed to implement this statutory provision in two ways. First, we proposed to use the precise statutory text in the introductory text in paragraph (10) under the definition of ''remuneration'' in 42 CFR 1003.110. Second, we proposed a condition at paragraph (10)(i) that interprets the statutory language so that the exception would be available only to the provider of services or the renal dialysis facility that is currently providing in-home dialysis, telehealth services, or other ESRD care to the patient. We explained that the intent of this condition was to ensure that the exception only protected the provision of telehealth technologies to patients with whom the provider or renal dialysis facility had a prior clinical relationship. A beneficiary has a prior clinical relationship with the donor if the patient is receiving home dialysis, telehealth services, or other ESRD care from the donor. We also specifically solicited comment on this interpretation recognizing that this limitation may pose challenges.

We also sought comment on but did not propose specific regulatory text for whether we should interpret the statutory exception to apply not only to the ''provider of services or the renal dialysis facility (as those terms are defined in title XVIII of the Act)'' but also ''suppliers,'' as defined in title XVIII of the Act, so that the exception would be consistent with the broader goals to expand patient access to in-home dialysis care furnished by their physician in section 50302(b) of the Budget Act of 2018.

Summary of Final Rule: We are finalizing, with modifications, the proposed condition at paragraph (10)(i) that interprets the statutory language so that the exception would be available only to the provider of services or the renal dialysis facility that is currently providing in-home dialysis, telehealth services, or other ESRD care to the patient. The final rule limits the exception to telehealth technologies furnished by a provider of services, physicians, or a renal dialysis facility currently providing in-home dialysis, telehealth services, or other ESRD care to the patients or has been selected or contacted by the patient to schedule an appointment or provide services.

Comment: Several commenters supported both of our proposals implementing section 1128A(i)(6)(J) of the Act, including the interpretation that the provision of telehealth technologies is limited to patients with whom the donors have a prior clinical relationship. Several commenters shared OIG's concern that expanding the exception to protect the provision of telehealth technologies to new patients or to patients who are not currently receiving ESRD services or care from the individual or provider of services or the facility may result in inappropriate steering.

However, another commenter expressed concern that this interpretation would be operationally difficult to implement and could reduce the benefits of the otherwise permissible telehealth technologies. According to the commenter, once patients have selected a provider, they should not have to wait for telehealth services furnished through protected arrangements until they are already receiving in-home dialysis. The commenter asserted that delaying telehealth technologies in this context may disrupt normal care delivery methods.

Response: Consistent with section 1128A(i)(6)(J) of the Act and our proposed interpretation, limiting the exception to telehealth technologies furnished by a provider of services, physicians, or a renal dialysis facility currently providing in-home dialysis, telehealth services, or other ESRD care to the patients is consistent with the statutory language and an appropriate safeguard against inappropriate steering and patient recruitment. As such, we are finalizing the introductory language of paragraph (10) under the definition of remuneration in 42 CFR 1003.110 as proposed.

We also are finalizing the condition at paragraph (10)(i) under the definition for ''remuneration'' in 42 CFR 1003.110 with modifications. Specifically, we have modified this condition by adding the following clause: ''or has been selected or contacted by the individual to schedule an appointment or provide services.''

We agree with the commenter who suggested that once a patient has selected a provider, physician, or facility, the patient should be eligible to receive telehealth technologies. The purpose of the proposed condition was to limit the risk of the technologies being used as a recruiting tool or to facilitate the provision of unnecessary services. However, because protected telehealth technologies may not be offered as part of any advertisement or solicitation, we believe that making telehealth technologies available to patients who contact the provider, physician, or facility on their own initiative is sufficiently low risk to warrant protection by this exception. Thus a provider, physician, or facility may offer or furnish telehealth technologies to a patient with ESRD who is receiving home dialysis paid for by Medicare Part B after the patient selects and initiates contact with a provider, facility, or physician to schedule an appointment or other services.[153] This approach is consistent with our intent in the OIG Proposed Rule to prevent arrangements from being protected by the exception where the donor does not have a preexisting clinical relationship with the patient and to reduce the risk of inappropriate patient recruitment or marketing schemes.

We view a patient reaching out to schedule an appointment or other services and asking whether assistance in facilitating telehealth services might be available as low risk in light of the other conditions in the exception, such as the limitation on advertisement and solicitation discussed further below. Patient-initiated contact is also distinguishable from a provider, facility, or physician initiating contact with a new patient (or to the patient's case manager) and soliciting the patient to elect in-home dialysis or to switch providers, coupled with an offer of telehealth technologies. The former would be protected (if all other conditions of the exception are met) and the latter would not.

Comment: Several commenters opposed extending the exception to apply to suppliers as defined in title XVIII of the Act because it could result in telehealth technologies being offered to patients without any provider reviewing whether the technology is an appropriate offering for the particular patient's clinical condition and, more generally, increases the risk for

[153] If a patient is unable to call a provider or physician himself or herself, or has otherwise given consent for a person (*e.g.,* a family member, a case manager, or a provider or supplier when the patient is attending an appointment or receiving services) to schedule appointments or upcoming services for him or her, then a request for an appointment or upcoming services made on behalf of the patient is sufficient to meet the patient-initiated contact requirement.

inappropriate use or offering of technologies. A commenter also asserted that expanding protected donors to include protection for suppliers is not consistent with congressional intent. A commenter asserted that protection under the exception should be limited only to nephrologists and dialysis providers who are directly responsible for the provision of care to home dialysis patients.

Response: This final exception, consistent with our solicitation in the OIG Proposed Rule, protects telehealth technologies provided by physicians as defined in title XVIII of the Act who are providing in-home dialysis, telehealth services, or other ESRD care to the recipient. This modification will be included in the introductory language of paragraph (10) and in paragraph (10)(i) under the definition to remuneration in 42 CFR 1003.110. As explained in the OIG Proposed Rule and further below, this modification is consistent with section 50302 of the Budget Act of 2018. In particular, physicians—notably but not exclusively nephrologists—are central to the provision of telehealth services related to ESRD care that would be furnished using the telehealth technologies, as described in the statute. For example, without the inclusion of physicians, telehealth technologies furnished by a patient's nephrologist could not receive protection under this exception.

As part of the Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2018,[154] section 50302 of the Budget Act of 2018 amends section 1881(b)(3) of the Social Security Act to permit an individual with ESRD receiving home dialysis to elect to receive their monthly ESRD-related clinical assessments via telehealth, if certain other conditions are met. CMS implemented these statutory changes through amendments to 42 CFR 410.78 and 414.65.[155] Under those CMS rules, the newly covered monthly ESRD-related clinical assessments furnished via telehealth would be provided by a physician at the distant site who is licensed under State law to furnish the covered monthly ESRD-related clinical assessments.[156] It is consistent with the OIG Proposed Rule and section 50302 of the Budget Act of 2018 that this exception protect the provision of telehealth technologies offered by physicians (*e.g.,* nephrologists) furnishing monthly ESRD-related clinical assessments via telehealth for patients receiving home dialysis. Under the new CMS rules, the physicians performing these clinical assessments are well positioned to understand what telehealth technologies should be provided to the ESRD patient for the purpose of furnishing telehealth services.

We agree with commenters that expanding the exception to a broad range of practitioner types by using ''suppliers'' poses risk and, upon further review, we see no support in the statute for doing so. Section 1128J(i)(6)(J) of the Act conditions protection on the connection between the provider of services or renal dialysis facility and caring for an individual with ESRD. The definition of ''suppliers'' in title XVIII includes a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title. That definition covers numerous practitioner and entity types, many of which are not providing ESRD services. We are concerned that including these practitioners and entities would not further the ESRD-related purposes of the exception, were not contemplated by Congress, and could pose risk that these parties would offer telehealth technologies to steer beneficiaries to select them as a supplier or to their products and services. In light of that risk and consistent with the section 1128J(i)(6)(J) of the Act, we are finalizing the exception by including ''physicians'' but not ''suppliers'' (as that term is defined in title XVIII).

Section 1861(r) of the Act defines the term ''physician.'' That definition includes a limited set of practitioners including doctors of medicine or osteopathy, doctors of dental surgery, doctors of podiatric medicine, doctors of optometry, and chiropractors. Under this final exception, a physician must meet this definition in 1861(r) of the Act and, consistent with paragraph 10(i) in 42 CFR 1003.110, be providing in-home dialysis, telehealth services, or other ESRD care to the patient. Consequently, it is unlikely that all practitioner types under 1861(r) would be eligible for protection for providing telehealth technologies under this exception. For example, it is unlikely that dental surgeons, doctors of podiatric medicine, or chiropractors would be providing telehealth services to ERSD patients.

d. Prohibition on Advertisement or Solicitation

Summary of OIG Proposed Rule: We proposed to incorporate the statutory requirement in section 1128A(i)(6)(J)(i) of the Act that the telehealth technologies are not offered as part of any advertisement or solicitation. We proposed to interpret the terms ''advertisement'' and ''solicitation'' consistent with their common usage in the health care industry.

Summary of Final Rule: We are finalizing this condition as proposed.

Comment: A commenter expressed support for the proposal precluding the protection of telehealth technologies offered as part of an advertisement or solicitation.

Response: We are including this protection in the final rule, consistent with the statute. As stated in the OIG Proposed Rule, we interpret the terms ''advertising'' and ''solicitation'' consistent with prior rulemakings. We emphasize that whether a particular means of communication constitutes an advertisement or solicitation will depend on the facts and circumstances.[157]

Additionally, consistent with our interpretation in the OIG Proposed Rule, we note that it is important for patients to receive information about their health care options, and that not all information provided to beneficiaries is advertising or solicitation. Stakeholders should interpret the terms ''advertisement'' and ''solicitation'' consistent with their common usage in the health care industry.

e. Provided for the Purpose of Furnishing Telehealth Services Related to an Individual's End Stage Renal Disease

Summary of OIG Proposed Rule: We proposed to interpret the condition at section 1128A(i)(6)(J)(ii) of the Act that the telehealth technologies are provided ''for the purpose of furnishing telehealth services related to the individual's [ESRD]'' to mean that the technologies: (i) Contribute substantially to the provision of telehealth services related to the individual's ESRD; (ii) are not of excessive value; and (iii) are not duplicative of technology that the beneficiary already owns if that technology is adequate for telehealth purposes. We proposed to interpret ''telehealth services related to the individual's ESRD'' to mean only those telehealth services paid for by Medicare

[154] S. 870, 115th Congress (Sept. 26, 2017).

[155] 83 FR 59495 (Nov. 23, 2018).

[156] 42 CFR 410.78(b) specifies in part that ''Medicare Part B pays for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system if the following conditions (are met, such as) . . . [t]he physician or practitioner at the distant site must be licensed to furnish the service under State law. The physician or practitioner at the distant site who is licensed under State law to furnish a covered telehealth service described in this section may bill, and receive payment for, the service when it is delivered via a telecommunications system.''

[157] 81 FR 88373 (Dec. 7, 2016).

Part B. We stated that we would consider technology to be of excessive value if the retail value of the technology were substantially more than required for the telehealth purpose.

We sought comment on but did not propose regulatory text on the following issues: (i) Whether we should require that the person furnishing the telehealth technologies make a good faith determination that the individual to whom the technology is furnished does not already have the necessary technology and that such technology is necessary for the telehealth services provided; (ii) whether we should adopt a more restrictive exception that would protect technologies that provide the beneficiary with no more than a *de minimis* benefit for any purpose other than furnishing telehealth services related to the individual's ESRD; (iii) whether we should adopt a different standard that would protect telehealth technologies only when furnished predominantly for the purpose of furnishing telehealth services related to the individual's ESRD; and (iv) whether the exception should require the provider or facility to retain ownership of any hardware and make reasonable efforts to retrieve the hardware once a beneficiary no longer needs it for the permitted telehealth purposes.

Summary of Final Rule: We finalizing this condition, with modification, to use the statutory language in section 1128J(i)(6)(J)(ii) of the Act. We are finalizing this condition consistent with the statutory exception to read: The telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end-stage renal disease.

Comment: Several commenters supported our interpretation of section 1128A(i)(6)(J)(ii) of the Act as proposed. Commenters appreciated what they believed to be meaningful guardrails to ensure that the provision of telehealth technology does not serve as an inducement to select a particular provider and shared our concerns regarding the potential for providers to offer such remuneration to steer patients with whom they do not have a prior clinical relationship to themselves.

Some commenters argued that our proposed interpretation of ''for the purpose of furnishing telehealth services related to the individual's [ESRD]'' was more restrictive than the statutory language required. For example, a commenter supported removing the word ''substantially'' from the phrase ''contributes substantially to the provision of telehealth services,'' observing it adds a restriction that does not appear expressly in the statute.

A commenter noted that certain telehealth technologies may have some benefit to a patient beyond facilitating telehealth services related to the individual's ESRD, but most uses can be limited from a technical standpoint. For those services for which it would not be feasible to limit use, such as data services, the commenter believed that such services could be provided based on a patient's clinical need, geographic need, or both, and removed when the patient no longer has a clinical or geographic need for the services (*e.g.,* the patient is no longer treated in the home).

Response: We are not finalizing our proposed language. Instead, we are modifying this condition to use the statutory language in section 1128J(i)(6)(J)(ii) of the Act. We agree with commenters that the proposed condition added additional requirements not included in the statute. To the extent that the exception needed additional safeguards, the Secretary has the authority to implement those under section 1128J(i)(6)(iii) of the Act. Therefore, we are finalizing this condition consistent with the statutory exception to read: The telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end-stage renal disease.

As explained in the OIG Proposed Rule, we have concerns about the provision of valuable technology improperly inducing a beneficiary to choose a particular provider, physician, or facility. The limited nature of the exception and the conditions finalized in this rule provide reasonable and necessary safeguards against fraud and abuse. For example, the conditions at paragraphs 10(i) and (ii) work together to prevent protection under the exception if the provider, physician, or renal dialysis facility is marketing or using the potential provision of technology to induce and obtain new patients.

Based on the statutory language and matching condition finalized here, we believe a wide range of technologies could be protected. However, we emphasize that a determination regarding whether the provision of telehealth technologies meets the condition at paragraph 10(ii) in the definition of ''remuneration'' at 42 CFR 1003.110 requires a case-by-case assessment of the functionality of the technologies to be provided and telehealth services being furnished to the ESRD patient.

We are not including a condition as suggested by the commenter that would require a donor to technically limit the telehealth technologies provided. Under this condition and the definition of ''telehealth technologies'' as finalized, technologies that are multifunctional and have purposes in addition to furnishing telehealth services related to the individual's ESRD are not precluded and may be protected. For example, this condition could protect a tablet that a patient would use to access telehealth services for their ESRD care, even though the tablet has other purposes or functionalities (*e.g.,* ability to download any mobile application) as long as such provision meets all conditions of the exception.

Comment: Several commenters opposed OIG's considered interpretation of this statutory condition—''the telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's [ESRD]''—that would restrict telehealth technologies to those that do not provide the beneficiary with more than a *de minimis* benefit outside of the telehealth services related to the individual's ESRD. Commenters suggested that such a condition would limit access to needed technology, add unnecessary burden and uncertainty, or impede the objective of expanding in-home dialysis patients' use of telehealth services. A commenter recognized that allowing devices with non-health care functions could be considered an inducement but highlighted that patients who receive such devices also must accept the obligations and responsibilities of home dialysis, which the commenter believes serves as an appropriate safeguard.

Another commenter expressed concerns that the *de minimis* benefit standard might create complications for patients with multiple health needs that could be fulfilled by the same device, and the commenter asserted that it would not be a good use of resources for a patient to be prescribed two separate digital health tools when one would meet all of the patient's clinical needs.

Response: We agree with commenters and are not finalizing a *de minimis* benefit standard in this exception.

Comment: Several commenters supported prohibiting providers from giving patients telehealth technologies for home dialysis that are of excessive value or duplicative of technology that the beneficiary already owns. A commenter found these guardrails particularly important given the limited number of vendors currently offering home dialysis equipment and supplies. The commenter asserted that the limited competition in the home dialysis market would make acquisition costs of telehealth technologies particularly

significant for small and independent providers who lack market share advantages used in negotiations with vendors. Another commenter requested further clarification on what donations would be considered of ''excessive value.''

Response: For the reasons noted above, we are finalizing paragraph (10)(iii) in 42 CFR 1003.110 to mirror the statutory language at section 1128J(i)(6)(J)(ii) of the Act, without a requirement that the telehealth technologies not be of excessive value. Additionally, we are not finalizing a condition elsewhere that requires the telehealth technologies not be of excessive value. The limited nature of the exception and the other conditions provide appropriate safeguards.

The value of the telehealth technologies provided to a patient may be a fact or circumstance used to assess whether the provision of such technology meets the finalized condition at paragraph 10(iii) in the definition of ''remuneration'' at 42 CFR 1001.130. In other words, depending on the facts and circumstances, technology of excessive value could indicate that the technology is not being provided for the purpose of furnishing telehealth services related to the individual's ESRD. Excessively valuable technology beyond what is reasonable for furnishing telehealth services related to ESRD could also indicate that the technology is part of a prohibited advertisement or solicitation under paragraph (10)(ii).

As stated in the OIG Proposed Rule, providing telehealth technology with substantial independent value might serve to inappropriately induce the beneficiary. In the context of this exception, that risk materializes because excessive value of the telehealth technology may make the purpose of the donation suspect and call into question whether it is related to furnishing telehealth services. For example, if a $50 per month data plan would facilitate the connection needed for the patient to access telehealth services, the provision of a $100 per month data plan might raise concerns that the data plan is being offered for a purpose other than access to telehealth services. Similarly, if the donor knows that the patient already has a data or internet service plan that would facilitate the furnishing of telehealth services and furnishes such a plan anyway, a question could arise about the purpose of the remuneration to the patient.

Comment: A commenter stated that if telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end-stage renal disease, and if the donated telehealth technologies meet the other elements of the exception, no dollar value limit should be necessary because the purpose cannot be to induce beneficiaries to select particular providers. Two other commenters recommended including a condition requiring the recipient's payment of at least 15 percent of the offeror's cost for the in-kind remuneration. Another commenter recommended a $500 annual cap to ensure the technology did not act as an inducement for referrals.

Response: We did not propose a contribution requirement or an annual monetary cap. We believe the combination of safeguards we are finalizing implement the statutory conditions in section 1128A(i)(6)(J) of the Act and safeguard against risks of fraud and abuse.

Comment: Related to the proposed requirement that the telehealth technologies be necessary and nonduplicative of technology the patient already has, a commenter stated that a patient's existing personal use technology may have some of the necessary capabilities but also may lack all components necessary to be reliable and fully functional for accessing telehealth services. The commenter further asserted it would not be efficient or practical to require that the provider furnish additional necessary components to the patient's existing technology—and any associated installation and support services—to make it fully capable of accessing telehealth services. For example, the commenter referenced a patient who has a personal computer without video capabilities. The commenter surmised that it is more logical and cost-effective to provide a ready-to-use integrated device focused solely on their ESRD clinical assessments and related ESRD care support to the patient instead of trying to retrofit the computer, which could involve identifying and installing missing components and providing technological support for this personal-use equipment. The commenter recommended that if the patient's personal technology does not have all the necessary components for telehealth, provision of fully integrated telehealth technology should be protected under the exception.

Response: We are not finalizing a requirement that the telehealth technologies not be duplicative of technology that the beneficiary already owns in paragraph 10(iii) in the definition of ''remuneration'' at 42 CFR 1001.130. This condition is being finalized consistent with the statutory condition at section 1128J(i)(6)(J)(ii) of the Act. Additionally, we are not finalizing a condition elsewhere that requires the telehealth technologies not be duplicative of technology that the beneficiary already owns. The limited nature of the exception and the other conditions provide appropriate safeguards.

Assessing whether telehealth technologies would be duplicative of technology that the beneficiary already has may be a fact or circumstance used to determine whether the provision of such technology meets the finalized condition at paragraph 10(iii) in the definition of ''remuneration'' at 42 CFR 1001.130. For example, if a patient has existing telehealth technology and is already able to receive telehealth services, providing the patient with additional telehealth technology may not have the purpose of furnishing telehealth services. A true determination would have to be based on the specific facts and circumstances of the additional provision of telehealth technologies, including the telehealth services provided to the patient and the patient's condition.

We highlight that if a patient's existing technology does not have all the necessary components or capabilities to support the telehealth services, then those facts are favorable in determining that the provision of telehealth technology to that patient meets the condition at paragraph (10)(iii). With respect to the decision between ''retrofitting'' a patient's existing technology or providing fully integrated telehealth technology, meeting this exception is not specifically conditioned on whether the technology is fully integrated or retrofitted. In making a determination about the technology to provide and potential protection under this exception, providers, physicians, and renal dialysis facility will have to assess the particular facts and circumstances for that patient and the potential technology. To be clear, we do not intend for this exception to result in providers, physicians, and renal dialysis facilities that provide telehealth technologies attempting to retrofit a patient's existing technology. To the extent that technology already owned or used by a patient with ESRD would not be adequate for the telehealth services, that fact weighs favorably in determining that providing new telehealth technology meets the condition at 10(iii) under the definition of ''remuneration'' in 42 CFR 1003.110.

Comment: Many commenters objected to the proposed additional requirement that the party furnishing the technology make a good faith determination that the

individual to whom the technology is furnished does not already have the necessary telehealth technology. Some commenters stated that the primary proposal—that the technology is not of excessive value and is not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes—provides adequate protection against technologies being used as inducements for duplicative or unnecessary telehealth services. Other commenters supported the proposed ''good faith determination'' requirement. Another commenter asked us to clarify what a ''good faith'' effort to determine that the patient does not have the necessary technology means, because the commenter is concerned that this provision could lead to increased physician burden. A commenter stated that requiring facilities or providers to make a good faith determination regarding whether the recipient already has access to telehealth technologies places a potentially ongoing burden to investigate a home dialysis patient's personal life to ensure that they do or do not possess such technology. The commenter asked whether a facility or provider must consistently audit patient technology access to ensure that the loaned or donated technology does not become duplicative over time. The commenter suggested that patients should be able to opt out of telehealth technologies furnished by a provider or facility, even if specified in their plan of care, because they already have access to such technology. In this way, the responsibility falls to the patient to report access to technology, not on the facility or provider to ensure that the patient does or does not possess such a device. Some commenters supported the proposed additional ''good faith determination'' requirement.

Response: We are not including a condition in this final exception that requires a good faith determination that the individual to whom the technology is furnished does not already have the necessary telehealth technology. Consistent with the discussion related to the condition on duplicative technology, we note that assessing whether providing telehealth technologies would be duplicative of technology that the beneficiary already has may be a fact or circumstance used to determine if the provision of such technology meets the finalized condition at paragraph 10(iii) in the definition of remuneration at 42 CFR 1003.110.

In response to the commenters' questions regarding what constitutes a good faith effort, we want to clarify that this exception does not condition protection on investigating the patient's personal life or auditing the technology that a patient may already have available. When determining whether the provision of telehealth technology meets this condition, specific facts and circumstances about the patient will need to be considered. This would include the patient's health condition, telehealth services provided to the patient, and how the telehealth technologies support furnishing telehealth services relating to the patient's condition. Most of the information about the patient is likely gathered as part of the clinical and monthly assessments that patients receiving in-home dialysis receive or is gathered through the normal course of patient and provider interaction about the patient's condition and treatment.

That said, nothing in this exception prevents physicians, providers, and facilities from asking patients about their existing technology needs and capabilities; nothing requires patients to answer such inquiries. We would expect that conversations about patients' existing technology would inform donors' decision-making with respect to furnishing telehealth technologies consistent with this exception. We do not prescribe how providers, physicians, and facilities make the determination whether providing telehealth technologies meets the condition that the technology be for the purpose of furnishing telehealth services related to the patient's ESRD.

As modified, we do not believe this final exception will increase provider, physician, or renal dialysis facility burden, nor expose patients to unwarranted intrusions. Conditions of this exception implement the statutory exception in section 1128A(i)(6)(J) of the Act. The statutory exception gives providers, physicians, and renal dialysis facilities the flexibility to provide telehealth technologies for the purpose of furnishing telehealth services related to patients' ESRD. This may help increase options for ESRD patients to manage their care by making telehealth more widely available. We also note that use of this exception is voluntary.

Comment: A commenter recommended that as a condition for protection, the telehealth technology provided to the patient should be necessary for the provision of the telehealth services and, where possible, restricted to the functions that facilitate the provision of care (*e.g.,* a tablet that can only be used for telehealth services), and ensure a secure, safe, and satisfactory user experience. However, the commenter explained that some telehealth technologies may be duplicative or overlap with technology the patient may already have access to and that the condition may result in an overly burdensome patient intake process, to include an accounting of all of the patient's technology (*e.g.,* items in a patient's possession as well as the operating systems and compatibility with the telehealth offering). The commenter suggested that instead of protecting only nonduplicative telehealth technologies, OIG limit protected telehealth technologies to what is reasonably necessary for the furnishing of telehealth services and require that providers, suppliers, and facilities provide the patient with disclosure language that the telehealth equipment is provided for their ESRD-related treatment and care, and that it is the responsibility of the patient to use the device for these specific purposes only.

Response: We did not propose a condition that the telehealth technology be necessary for the provision of telehealth services and are not finalizing such a condition. As explained above, we are also not finalizing a condition that requires a good faith determination that the individual to whom the technology is furnished does not already have the necessary telehealth technology. We emphasize telehealth technology is not protected unless the technology is provided for the purpose of furnishing telehealth services related to the individual's end-stage renal disease.

We are not finalizing the condition that would require the person who furnishes the telehealth technologies to take reasonable steps to limit the use of the telehealth technologies by the individual to the telehealth services described on the Medicare telehealth list. We agree with the commenter that there may be practical and operational challenges with such a requirement. Additionally, the combinations of safeguards finalized in this rule appropriately protect against potential fraud and abuse and this condition, which we considered in the OIG Proposed Rule, is not necessary.

Comment: A commenter expressed support for our proposal to interpret ''telehealth services related to the individual's [ESRD]'' to mean telehealth services paid for by Medicare Part B because the proposal ensures that all Part B telehealth services are treated consistently by defaulting to the statutory definition for telehealth services. Another commenter suggested that we clarify that, in order to qualify for protection under the exception, the telehealth technologies must be used for

the Part B clinical assessment and also may be used for additional clinical support and patient monitoring directly related to the ongoing ESRD care.

Many other commenters urged us not to adopt this interpretation, asserting that it was too narrow. Commenters noted that patients with ESRD could benefit from telehealth services that might not be covered by Part B—including patient education, dietary counseling, and monitoring vital signs—that may assist with managing comorbidities (which may or may not be related to the patient's ESRD) and preventing further progression of kidney disease. A commenter stated that while the care provided via telehealth technologies should be primarily related to the management of ESRD, dialysis providers are well-suited to treat the ''whole person'' with the assistance of telehealth technologies. The commenter sought to provide telehealth technologies that might support virtual ESRD management (*e.g.,* nurse assessment, social worker support, dietician care), as well as telehealth technologies that may address ESRD-related issues and comorbidities possibly included in value-based care models (*e.g.,* fistula evaluation and specialty visits for comorbidity management). Commenters also asserted that protecting a broader range of telehealth services would further the Department's goal of encouraging care coordination and Congress' intent in enabling in-home dialysis. Some commenters asserted that the statute does not require limiting the telehealth services to those paid for by Medicare Part B. A commenter also noted that payment for ESRD services under Medicare Part B is through a bundled payment and it is therefore impossible to have the technology tied to any particular reimbursed service.

Response: We are not finalizing our proposed interpretation of ''telehealth services related to the individual's [ESRD]'' to mean telehealth services paid for by Medicare Part B. We did not propose regulatory text to implement this interpretation, and therefore, are not making corollary modifications to the regulatory text. We explain in more detail below that we broadly interpret the term ''telehealth services'' to apply a wide range of services that are provided with telehealth technologies. However, we are not adopting a specific definition of ''telehealth services'' for this exception. We provide additional explanation about our interpretation of the term ''telehealth services'' below.

We agree with commenters that section 1128A(i)(J)(6) of the Act does not limit telehealth services to those paid for by Medicare Part B. The definition of ''telehealth technologies'' in section 1128A(i)(6)(J) and the term ''telehealth services'' in 1128A(i)(6)(J)(ii) are not limited to related definitions in Medicare. The statute provided the Secretary flexibility to interpret these terms differently than the Medicare definitions in Title XVIII of the Act.

Consistent with the statutory exception and for the purpose of this exception, we are not limiting the term ''telehealth services'' to those that would be paid for by Medicare Part B. We recognize that this means providers, physicians, and renal dialysis facilities will have flexibility to determine whether telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's ERSD. The limited nature of the exception and the other safeguards appropriately limit the risk of fraud and abuse. For example, one risk of inappropriate beneficiary inducements is that they will lead to a practitioner providing medically unnecessary services to the patient. The limited nature of this exception mitigates that risk (*e.g.,* this exception is limited to Medicare Part B beneficiaries receiving in-home dialysis). It is unlikely that a beneficiary could be induced to receive medically unnecessary in-home dialysis to receive free telehealth technologies. In-home dialysis is invasive treatment and requires significant up-front training.

Additionally, under the same sections the beneficiary must be receiving in-home dialysis paid for by Medicare Part B. That mitigates and provides additional protection against providers, physicians, and renal dialysis facilities that seek to use telehealth technologies to induce and bill for medically unnecessary telehealth services related to the patient's ESRD condition. If the provider is seeking to bill Medicare for telehealth services that use telehealth technologies protected by this exception, those services must meet all Medicare requirements, including medical necessity. This exception does not affect Medicare requirements for ESRD services or telehealth services. Furthermore, billing for medically unnecessary telehealth services is not protected by this exception and such conduct would implicate criminal and civil health care fraud statutes. Therefore, this exception does not need to link the term ''telehealth services'' to those paid for by Part B as an additional safeguard for the purposes of this exception. To the contrary, we agree with commenters that limiting telehealth services to services currently paid for by Medicare Part B would unnecessarily limit the utility of the exception to support patients' ESRD care and use of home dialysis. To the extent that the telehealth services are not billable to Medicare, there is reduced risk that free telehealth technology is being offered as an inducement for billable services.

We are not finalizing a definition of ''telehealth services'' specific for this exception. Instead, we are providing an interpretation of the term in the preamble of this rule. The exception protects the provision of a broad range of telehealth technologies, as we explained above in the discussion of that definition. If we were to limit the term to telehealth services paid for by Medicare Part B, then the types of technology would be limited to those identified in section 1834(m) of the Act and 42 CFR 410.78 (*i.e.,* audio and video equipment permitting two-way, real-time interactive communication). Similarly, if we were to define ''telehealth services,'' we might inadvertently limit the scope of the telehealth technologies definition that is intended to be broad.

As stated previously, we intend for this exception to apply to all types of telehealth technology that are provided for the purposes of furnishing distant or remote services through various modalities. At a minimum, such services include the following types covered by Medicare: Telehealth services, virtual check-in services, e-visits, remote care management, and remote patient monitoring. To receive protection, telehealth technologies do not need to be provided for the purpose of furnishing a payable Medicare service related to the individual's end-stage renal disease.

To provide additional examples, this exception would protect telehealth technology provided for the purpose of furnishing the following types of telehealth services raised by commenters as long as the arrangement meets all conditions of the exception: Virtual ESRD management (*e.g.,* nurse assessment, social worker support, dietician care), patient education, dietary counseling, and monitoring vital signs. Other services not listed here may also be considered telehealth services for the purposes of this exception based on the facts and circumstances of the care being provided. Accepted clinical and care practices for use of telehealth, physician judgment, and patient and caregiver needs and preferences with respect to modalities would be relevant considerations in assessing the telehealth services under this specific condition. This exception provides significant flexibility to providers,

physicians, and renal dialysis facilities to assess how telehealth technologies can be provided to support a wide range of telehealth services related to an individual's ESRD.

Again, this exception does not change the coverage or payment requirements related to the provision of these services or submitting claims for reimbursement. Even though this exception may protect a physician, provider, or renal dialysis facility from CMP liability for providing a patient telehealth technology for the purpose of furnishing telehealth services, that does not mean the physician, provider, facility, or any other individual or entity can bill for those services.

The other limitation in this condition is that the telehealth technologies be provided for the purposes of furnishing telehealth services related to the individual's ESRD. In response to commenters who recommended that this include telehealth services that address ESRD-related issues and comorbidities, we agree that this language is not specifically limited to ESRD. We recognize that patients with ESRD are likely receiving care for comorbidities that affect their ESRD. It would be difficult to define in this Beneficiary Inducement CMP exception criteria that a provider, physician, or renal dialysis facility could apply to assess whether a telehealth service is or is not related to an individual's ESRD. We believe the appropriate approach is to give health care providers flexibility to make this determination reasonably based on the specific facts and circumstances of the patient's condition and telehealth services furnished to care for such condition. Although not required, we believe it would be a best practice for the donor to document contemporaneously how the telehealth services relate to the individual's ESRD care, such as to management of care, monitoring of health, or treatment, potentially including reference to appropriate clinical or other relevant health or patient-reported indicators.

Furthermore, we note that several other exceptions and safe harbors may apply to certain items and services for which commenters sought protection under this exception, depending on the facts and circumstances, such as the patient engagement and support safe harbor finalized in this rule at 42 CFR 1001.952(hh) and the exception to the definition of ''remuneration'' under the Beneficiary Inducements CMP for certain remuneration that poses a low risk of harm and promotes access to care, 42 CFR 1003.110.

f. Ownership and Retrieval of Technology

Summary of OIG Proposed Rule: In the OIG Proposed Rule, we considered and sought comment on a condition that would require the provider or facility to retain ownership of any hardware and make reasonable efforts to retrieve the hardware once the beneficiary no longer needs it for the permitted telehealth purposes.

Summary of Final Rule: After a consideration of relevant comments, we are not finalizing this condition.

Comment: Many commenters on this topic expressed support for the overall concept of requiring the provider or facility to retain ownership and make reasonable efforts to retrieve the hardware once the beneficiary no longer needs it. Some commenters did not support a requirement that the provider or facility retain ownership. Some of these commenters noted that the concept of ownership in this context may be rendered moot because the useful life of the device may expire during the period of use by the patient. Some commenters also questioned the utility of requiring retrieval of items that are no longer state-of-the-art or otherwise have minimal value. Many commenters also expressed concern regarding the administrative burden associated with tracking and monitoring compliance with a retrieval requirement.

Many commenters on this topic described potential scenarios in which technology may be provided to a patient who then ceases to need it (*e.g.,* the patient receives a transplant). In these circumstances, commenters were generally supportive of requiring the provider or facility to retrieve the technology. Several commenters supported requiring ''reasonable efforts'' to retrieve the hardware in circumstances when it will not harm the patient, with exceptions for circumstances when retrieval is impractical, the hardware has greatly reduced utility or value, or the patient has died. A commenter also asserted that if the hardware is provided in such a way that the use is limited to telehealth services, it will not provide substantial independent value to the beneficiary, and thus the failure to retrieve after reasonable recovery efforts does not create meaningful inducement risks.

Response: We are not finalizing a requirement that a provider, physician, or facility retain ownership of the technology. We also are not finalizing a retrieval requirement. We note that the condition that the telehealth technologies be provided to an individual with ESRD and who is receiving home dialysis for which payment is being made under Medicare Part B would necessitate termination of technology services (*e.g.,* recurring monthly data plan fees or applications that require ongoing subscription fees) if the individual is no longer receiving home dialysis payable by Medicare Part B. Likewise, technology services would need to be terminated if the patient is no longer using them for ESRD-related telehealth services. Further, the exception does not protect sham donations of technology given to individuals to keep indefinitely.

g. Prohibition on Cost-Shifting

Summary of OIG Proposed Rule: We proposed to require as a condition of protection under the exception that the provider of services or a renal dialysis facility not separately bill Federal health care programs, other payors, or individuals for the telehealth technologies, claim the costs of the telehealth technologies as a bad debt for payment purposes, or otherwise shift the burden of the costs of the telehealth technologies to a Federal health care program, other payors, or individuals.

Summary of Final Rule: We are not finalizing this condition.

Comment: Commenters expressed support for the proposed prohibition on cost-shifting. No commenters expressed opposition.

Response: Upon consideration of the combination of safe harbor conditions implemented by this final rule, we are not finalizing the proposed cost-shifting prohibition. We have concluded that the combination of final conditions and the limited-nature of this statutory exception will adequately protect against fraud and abuse risks, and an additional safeguard related to cost-shifting is not necessary.

We proposed the cost-shifting condition to protect against the telehealth technologies resulting in inappropriately increased costs to Federal health care programs, other payors, and patients. However, we do not want to exclude arrangements from this exception that involve furnishing telehealth or other service to the ESRD patient receiving in-home dialysis and that are also billable to Medicare. We recognize that those services, as long as applicable Medicare rules are met, may appropriately result in Medicare paying for costs of certain telehealth technologies or an appropriate increase in certain Medicare costs.

We did not intend to suggest any limit on appropriate billing of Federal health care programs or other payors for

medically necessary items and services furnished in connection with telehealth technologies provided to ERSD patients receiving in-home dialysis. If a provider furnishes items or services that are covered as part of a Federal health care program, the provision of those items or services alone would not implicate the Federal anti-kickback statute at all. However, there could be circumstances under which a provider, when furnishing covered items or services, does give a Federal health care program beneficiary something of value, or remuneration, thereby implicating the Federal anti-kickback statute. For example, the Federal anti-kickback statute would be implicated by a provider waiving or reducing any required cost-sharing obligations for the covered items and services incurred by a Federal health care program beneficiary or providing ''extra'' items and services—that is, that are not part of the covered item or service—for free. Furthermore, nothing in this rule exempts parties from responsibility for compliance with all applicable coverage and billing rules.

Additionally, this final exception covers a wider range of telehealth technologies used to support the furnishing of telehealth services than types of technology used to provide Medicare Part B covered ''telehealth services.'' There may be other Medicare covered services that would cover the costs of telehealth technologies, as defined in this exception, as part of a service provided to a beneficiary receiving in-home dialysis. For example, the remote patient monitoring services described by the chronic care remote physiologic monitoring family of codes are covered by Medicare Part B but are not ''telehealth services'' within the meaning of the Medicare statute. However, remote patient monitoring technologies would meet the definition of ''telehealth technologies'' in this final exception.

h. Other Potential Safeguards

i. Consistent Provision of Telehealth Technologies

Summary of OIG Proposed Rule: The OIG Proposed Rule considered several other potential conditions for this exception, including prohibiting providers and renal dialysis facilities from discriminating in the offering of telehealth technologies. We solicited comments on this potential safeguard and whether it would limit the ability of providers and facilities to offer technologies due to the potential cost of furnishing the technology to all qualifying patients rather than a small subset. We also solicited comments on why offering technology to a smaller subset of qualifying patients might be appropriate and not increase the risk of fraud and abuse.

Summary of Final Rule: We are not finalizing this condition.

Comment: A few commenters supported some form of a nondiscrimination standard as appropriate. On the other hand, several commenters raised concerns regarding a possible condition to the exception requiring that a provider or facility provide the same telehealth technologies to any Medicare Part B patient receiving in-home dialysis, or to otherwise consistently offer telehealth technologies to all patients, including that the uniform provision of telehealth technologies would be cost-prohibitive for many providers and facilities and could result in their decision not to offer any telehealth technologies. Several commenters encouraged us to adopt more flexible standards that would allow the provider or facility to exercise discretion in offering telehealth technologies to ensure that the patients to whom they offer the technologies are most likely to benefit from them.

At least one of these commenters suggested that providers and facilities be permitted to provide telehealth technologies differentially to patients based on clinical risk assessments, clinical appropriateness determinations from the patient's physician, or other clinical or means-based criteria, with another commenter noting that it is common for providers and payors to focus interventions on higher risk or higher cost patients. A dialysis provider specified that they would like the exception to protect the deployment of certain technologies, such as remote monitoring or wearable devices, to specific patient populations that may have higher assessed clinical risk, such as patients that have experienced a recent hospitalization event.

Other commenters supported the approach of requiring providers or facilities to consistently offer telehealth technologies to all patients satisfying specified, uniform criteria, and a commenter requested that we make clear that a provider or facility would have flexibility to establish criteria under which only a subset of patients would be offered telehealth technologies. A commenter noted that legitimate criteria may include for example patient mobility, access to transportation options, financial status, and health condition. A commenter suggested that we identify and carve out criteria that would not be appropriate, such as the patient's payor or provider.

A dialysis provider encouraged OIG to ensure flexibility to provide and customize certain telehealth technology offerings to patients based on for example means-based or rural location needs, and to allow for changes resulting in the development of new technology. The commenter noted that the availability and cost of data plans and devices with wireless cellular service may vary from location to location, and thus a requirement to furnish the same telehealth technologies to all patients may not be feasible.

Response: We appreciate the comments that explain why providing the same telehealth technologies to any Medicare Part B eligible patient receiving in-home dialysis may be impractical or impossible, and we are not finalizing that condition. We also are not finalizing a condition that would require providers, physicians, and facilities to consistently offer telehealth technologies to all patients satisfying specified, uniform criteria. As stated in section III.C.1.a above, this is a narrow statutory exception to the Beneficiary Inducement CMP. Because the exception finalized here is only available to established patients who are receiving specific services paid for by Medicare Part B, the potential for fraud and abuse is reduced.

We recognize that patient need for technology may vary based on location, availability of transportation, financial status, diagnosis and treatment plan, or other legitimate and appropriate factors. We believe the donor is in the best position to identify whether provision of the technology is appropriate only to a subset of patients receiving in-home dialysis paid for by Medicare Part B. We are providing additional flexibilities to donors to determine which beneficiaries receive telehealth technologies by not finalizing this condition. The risk of fraud and abuse associated with selectively deciding which patients receive telehealth technologies is mitigated by other conditions finalized in this rule (*e.g.,* telehealth technologies are protected only if provided to beneficiary already receiving in-home dialysis). Additionally, providers, physicians, and facilities must still meet Medicare requirements for services provided to the beneficiary; they cannot bill for medically unnecessary services. Schemes to submit false claims would implicate other criminal and civil fraud statutes and would not be protected by this exception to the Beneficiary Inducement CMP.

Comment: Several commenters encouraged us to adopt a standard that allows for providing technology on an as-needed basis, recognizing that some

patients may choose not to have telehealth services and some patients may prefer to use their own technology. Other commenters encouraged us to ensure patients retain the right to choose whether to participate in telehealth services or utilize telehealth technology.

Response: The design of the final rule allows providers to take into account patient choice and preferences. We are not finalizing a condition that would have required physicians, providers, and facilities to provide telehealth technologies in accordance with specified criteria applied uniformly. We agree with commenters that patient choice is paramount, and the decision to select a home dialysis modality or telehealth services related to the patient's ESRD rests with the patient. Patients are under no obligation to dialyze in the home or to receive telehealth services, notwithstanding the availability of telehealth technologies. We emphasize that protected telehealth technologies cannot be offered as part of an advertisement or solicitation, nor should offers of free telehealth technology be made for the purpose of persuading patients to make clinical decisions about treatment modalities. In such cases, the telehealth technologies are not being provided for the purpose of furnishing telehealth services as required by the statute and this exception.

ii. Notice to Patients

Summary of OIG Proposed Rule: In the OIG Proposed Rule, we stated that we were considering adding a condition that would require providers or facilities to provide a written explanation of the reason for the technology and any potential ''hidden'' costs associated with the telehealth services to any patient who elects to receive telehealth technology. We considered this condition in response to concerns raised in comments submitted in response to the OIG RFI [158] that patients may be confused by the technology or the reason they are receiving a piece of technology and may be unaware of costs associated with telehealth services. We sought comment on these perceived risks to patients, whether to include a written notice requirement in the final rule and, if so, what that notice should state.

Summary of Final Rule: For the reasons stated below, we are not finalizing this requirement.

Comment: Most commenters on this topic supported the principle of providing information to patients, but commenters disagreed as to whether we should adopt a formal notice requirement as a standard for meeting the exception. Some commenters asserted that there was no need for a formal notice requirement as a condition of the exception because this type of communication should be a part of the normal physician-patient relationship. Others stated that conveying this type of information is the current standard of medical practice for home dialysis patients. Other commenters supported having a formal notice requirement as a condition of the exception, emphasizing the need to ensure patients have a clear and transparent understanding of the care they are receiving and the costs of such care. A commenter requested that OIG provide a sample of any required notice.

Response: We agree that patients need to have a clear understanding of the care they are receiving and the costs of such care. However, we also agree with commenters that this information should be conveyed through the physician-patient relationship or in the normal facility-patient communications for patients dialyzing at home. We are not finalizing any notice requirement as part of the exception. Parties are free to provide written notice explaining the reason for the technology and any potential costs associated with the telehealth services if they so choose.

iii. Patient Freedom of Choice

Summary of OIG Proposed Rule: The OIG Proposed Rule considered a condition to the telehealth technologies exception designed to preserve patient freedom of choice among health care providers and the manner in which a patient receives dialysis services (*i.e.,* in-home or in a facility). Specifically, we considered adding a condition to the exception that would require offerors of telehealth technologies to advise patients when they receive such technology that they retain the freedom to choose any provider or supplier of dialysis services and receive dialysis in any appropriate setting.

Summary of Final Rule: As explained below, we are not finalizing this requirement.

Comment: Several commenters, while supportive of patient autonomy and ensuring that patients are aware of the right to choose practitioners, providers, suppliers, and dialysis modalities, disagreed with additional documentation requirements related to informing patients of these rights for a number of reasons. For example, one commenter suggested that patients may not wish to receive this information. The commenter advocated instead for broader protections for freedom of choice, such as a prohibition on restricting referrals. Other commenters highlighted the administrative burden of additional documentation. Commenters stated that notice already is part of the provider and patient relationship, noting that for certain facilities any additional documentation requirement would be duplicative of the notice requirements found in the ESRD Conditions for Coverage (CFCs). A commenter requested a carve-out for facilities that meet the requirement under the CFCs. A commenter asserted that it would not add sufficient value that outweighs the burden of providing a written explanation of the reason for the technology and any potential ''hidden'' costs associated with the telehealth services to any patient who elects to receive telehealth technology.

Other commenters supported the proposed requirement and asserted that patients should be informed that they have the choice whether to use technologies and that their choice will not in any way influence the care to which they are entitled. Another commenter suggested that this should be standard information given to patients receiving ESRD-related care, regardless of the treatment modality they use. The commenter shared a concern raised that some patients may be persuaded to opt for telehealth services due to generous telehealth technologies and services being offered rather than clinical appropriateness, and believes this step could prevent any such inappropriate care from occurring. One commenter proposed to further clarify that the patient notice or patient consent for use of telehealth technologies include that the patient is not required to utilize or accept the provision of such technologies.

Response: We are not finalizing this condition because we believe in part that existing laws are better suited to protecting patient freedom of choice and the patient's best interest than a statutory-based exception to the Beneficiary Inducement CMP, including those discussed by the commenters. Furthermore, discussion of clinical appropriateness of in-home dialysis and telehealth services related to a patient's ESRD is inherent in the physician-patient relationship or facility-patient relationship, which serves first-and-foremost to protect the patient's best interest and preserve patient choice. The condition finalized at paragraph (10)(i) in 1003.110 limits the offer or furnishing of telehealth technologies to a patient that initiates contact with the provider, facility, or physician to schedule an appointment or other

[158] 83 FR 43607 (Aug. 27, 2018).

service also supports patient autonomy, and marketing is not allowed by the condition at paragraph (10)(ii) in 1003.110. These conditions will help preserve a patient's choice to select any provider, physician, or facility without inappropriate influence from such entities.

Comment: A commenter supported informing recipients of their freedom to choose any provider or supplier of dialysis services but requested clarification regarding whether telehealth technologies furnished to certain in-home dialysis patients would also be covered under the exception to the definition of ''remuneration'' for items or services that promote access to care and pose a low risk of harm to Federal health care programs at 1128A(i)(6)(F) of the Act.

Response: As stated above, we believe existing laws are better suited to protecting patient freedom of choice and nothing in this rule limits patient's freedom of choice. As we stated in the OIG Proposed Rule, the provision of telehealth technologies might qualify for protection under other existing exceptions or safe harbors. Whether a particular arrangement for the provision of telehealth technologies meets the requirements of, for example, the exception for arrangements that promote access to care and poses low risk of harm at 1128A(i)(6)(F) of the Act (and the corresponding regulatory exception at 42 CFR 1003.110) is a fact-specific analysis beyond the scope of this rulemaking. We note that parties are also free to request an OIG advisory opinion.

iv. Materials and Records Requirement

Summary of OIG Proposed Rule: We did not propose a condition related to the development or retention of materials and records or another documentation requirement but solicited comments on the fraud and abuse risks presented by not including such a condition in this exception.

Summary of Final Rule: We are not finalizing a materials and records retention requirement.

Comment: Commenters agreed with our approach to omit a materials and records or other documentation requirement. A commenter noted that this approach reduces unnecessary administrative burden. Another commenter pointed to other documentation requirements required by law, highlighting that these obviate the need for a documentation requirement in this exception.

Response: We agree that omitting a documentation requirement for this exception may reduce administrative burden for donors of telehealth technologies. We believe that in the case of telehealth technologies provided to individuals with ESRD under this exception, the absence of a documentation requirement does not materially impact the attendant fraud and abuse risks. We note, however, that while this exception is voluntary, parties that rely on it have the burden of demonstrating that all the conditions are met. Maintaining documentation that the provision of telehealth technologies satisfies the exception's conditions may be prudent for compliance purposes.

a. Other Offerors

Comment: Several commenters stated that free and charitable clinics and charitable pharmacies, especially in rural areas, rely on the use of telehealth technologies to provide access to specialty care to uninsured and medically underserved patients. The commenters posited that eliminating barriers to allow free and charitable clinics and charitable pharmacies to furnish telehealth technologies to patients without implicating the physician self-referral law or the Federal anti-kickback statute would enhance their ability to serve the target population of uninsured and medically underserved. The commenters suggest that expanded access to telehealth technologies would enhance health equity and care coordination, specifically for those who are uninsured and in rural areas. Another commenter was supportive of the exception and suggested expansion to allow for the provision of telehealth technologies by behavioral health providers.

Response: We appreciate the commenters' suggestion that telehealth technologies may benefit a broader range of patients. Charitable clinics or charitable pharmacies that meet the conditions in paragraphs (10)(i) and (ii) (*e.g.,* a provider, physician, or renal dialysis facility that is currently providing the in-home dialysis, telehealth services, or other end-stage renal disease care to the patient or has been selected or contacted by the individual to schedule an appointment or provide services) may be eligible to protect the provision of telehealth technologies under this exception. Such a determination must be based on the facts and circumstance of the specific clinic or pharmacy, and whether the provision of the telehealth technology meets all conditions of the exception.

We note that several other exceptions and safe harbors may apply to the provision of telehealth technologies to patients, depending on the facts and circumstances, such as the patient engagement and support safe harbor, finalized in this rule at 42 CFR 1001.952(hh), and the exception to the definition of ''remuneration'' under the Beneficiary Inducements CMP for certain remuneration that poses a low risk of harm and promotes access to care, found at 42 CFR 1003.110.

j. Recipient

Comment: A commenter stated that it is critical to ensure that the provision without charge of these same technologies to nephrologists and other treating physicians of home dialysis patients is permissible under anti-kickback statute. The commenter highlighted that every dialysis patient is required to have an attending nephrologist, and the nephrologist is the only individual who is part of the required care team who is not otherwise employed by the dialysis provider. Accordingly, the commenter urged us to clarify that the dialysis provider can also provide members of the care team who are not employed by the dialysis provider with the technology and software necessary to accommodate telehealth for dialysis patients.

Response: We appreciate the commenter's concerns, but the commenter's recommendations are outside the scope of the statutory exception we codify here, which is an exception to the definition of ''remuneration'' under the Beneficiary Inducements CMP. Specifically, the regulatory exception we finalize here implements the corresponding statutory exception in section 50302 of the Budget Act of 2018, which protects the provision of telehealth technologies ''to an individual with end-stage renal disease. . . .'' This exception does not protect remuneration between a dialysis provider and other members of a patient's care team. As the commenter notes, remuneration among and between providers and practitioners may implicate the Federal anti-kickback statute. Parties seeking to protect such arrangements may seek protection under a safe harbor, such as the care coordination arrangements safe harbor finalized in this rule at 1001.952(ee). Parties are also free to request an advisory opinion pursuant to 42 CFR 1008 *et seq.* related to the facts and circumstances described in this comment.

Comment: A commenter requested clarity regarding situations in which technologies provided to beneficiaries could also result in potential indirect benefits to other providers who may be in a referral source relationship with the donor of the telehealth technologies,

including in the context of an integrated care delivery system.

Response: We appreciate the commenter's concern. The Federal anti-kickback statute is a criminal statute that serves as an important sanction against fraud when parties intentionally offer or pay kickbacks to influence referrals. Any indirect benefit to a provider who may be a referral source for a donor would need to be analyzed under the Federal anti-kickback statute which, as explained above, is outside the scope of the statutory exception to the Beneficiary Inducements CMP that we codify here. As a matter of law, arrangements that fit in an exception to the Beneficiary Inducements CMP are not automatically protected from liability under the Federal anti-kickback statute. Parties seeking to protect remuneration implicating the Federal anti-kickback statute should assess arrangements to determine if the arrangement qualifies for protection under a safe harbor.

IV. Provisions of the Final Regulation

This final rule incorporates the regulations and amendments we proposed in the OIG Proposed Rule, but with changes to the regulatory text. In this final rule, we modify existing as well as add new safe harbors pursuant to our authority under section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 by specifying certain payment practices that will not be subject to prosecution under the Federal anti-kickback statute. We also codify into our regulations a statutory safe harbor for patient incentives offered by ACOs to assigned beneficiaries under ACO Beneficiary Incentive Programs and a statutory exception to the definition of ''remuneration'' in 42 CFR 1003.110 for certain telehealth technologies furnished to in-home dialysis patients.

The following is a list of the safe harbors and the exception that we are finalizing: Modifications to the existing safe harbor for personal services and management contracts at 42 CFR 1001.952(d); modifications to the existing safe harbor for warranties at 42 CFR 1001.952(g); modifications to the existing safe harbor for electronic health records items and services at 42 CFR 1001.952(y); modifications to the existing safe harbor for local transportation at 42 CFR 1001.952(bb); a new safe harbor for care coordination arrangements to improve quality, health outcomes, and efficiency at 42 CFR 1001.952(ee); a new safe harbor for value-based arrangements with substantial downside financial risk at 42 CFR 1001.952(ff); a new safe harbor for value-based arrangements with full financial risk at 42 CFR 1001.952(gg); a new safe harbor for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency at 42 CFR 1001.952(hh); a new safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives at 42 CFR 1001.952(ii); a new safe harbor for cybersecurity technology and related services at 42 CFR 1001.952(jj); a new safe harbor for accountable care organization (ACO) beneficiary incentive program at 42 CFR 1001.952(kk); and an exception for telehealth technologies for in-home dialysis at 42 CFR 1003.110.

V. Regulatory Impact Statement

As set forth below, we have examined the impact of this final rule as required by Executive Order 12866, the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, Executive Order 13132, and Executive Order 13771. In section A, we provide an overview of our analysis of the impact of this final rule. We also provide additional supporting analysis in section F.

Summary of OIG Proposed Rule: We determined that the aggregate economic impact of the proposals would be minimal and would have no effect on the economy or on Federal or State expenditures. We also determined that the proposals would not significantly affect small providers. Further, we determined that the rule was neither regulatory nor deregulatory under Executive Order 13771.

Summary of Final Rule: We are finalizing the determinations set forth in the OIG Proposed Rule except for the determination under Executive Order 13771. Here we explain that this final rule is a deregulatory action under Executive Order 13771. In addition, we provide additional explanation about our determinations here.

A. Overview of Analysis

By making available the new protections established in this final rule, we expect health care industry stakeholders will realize increased flexibility and legal certainty when entering into value-based, care coordination, and other arrangements that have the potential to reduce Federal health care program expenditures and improve the quality of care without sacrificing program integrity. However, we are unable to quantify—with certainty—the overall aggregate impact or effect on small providers related to changes in industry behavior that we can reasonably expect following the effective date of this final rule. Even so, we believe that our final policies are reasonably likely to permit, if not encourage, behavior that will reduce waste in the U.S. health care system, including Medicare and other Federal health programs, and that these changes will result in lower costs for both patients and payors, and generate other benefits, such as improved quality of patient care and lower compliance costs for providers and suppliers. Below we describe: (1) The need for new and modified safe harbors and exceptions; (2) an overview of the estimated impact of the final rule; (3) anticipated outcomes of the final rule; (4) expanded protections under the final rule and examples of anticipated arrangements; (5) anticipated beneficial impact of value-based, care coordination, and patient engagement and support arrangements; (6) anticipated beneficial impact of the new safe harbor for cybersecurity technology and services; and (7) anticipated costs.

1. Need for New and Modified Safe Harbors and Exceptions

The Federal anti-kickback statute provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward, among other things, the referral of business reimbursable under any of the Federal health care programs, including Medicare and Medicaid. Health care providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to any Federal anti-kickback enforcement action. Compliance with an applicable safe harbor insulates an individual or entity from liability under the Federal anti-kickback statute. Parties may use any applicable safe harbor into which they can squarely fit.[159] However, failure to fit in a safe harbor does not mean that an arrangement violates the law.

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that

[159] Existing safe harbors that may apply to some care coordination and value-based arrangements include the employee safe harbor (42 CFR 1001.952(i)), the personal services and management contracts safe harbor (42 CFR 1001.952(d)), the various managed care safe harbors (*e.g.,* 42 CFR 1001.952(t)), and the local transportation safe harbor (42 CFR 1001.952(bb)). However, stakeholders have informed us that many arrangements they would like to enter into cannot fit in the existing safe harbors as currently structured.

the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). Compliance with an applicable exception to the definition of ''remuneration'' under the Beneficiary Inducements CMP or compliance with an exception or safe harbor to the Federal anti-kickback statute protects such practice from liability under the Beneficiary Inducements CMP.

In many cases, emerging coordinated care and value-based delivery and payment arrangements, which encourage functional integration and coordination between and among providers and other industry stakeholders, often using financial incentives, may not fit easily or at all under current safe harbors to the Federal anti-kickback statute, exceptions to the Beneficiary Inducements CMP, or both. Many value-based and care coordination arrangements also rely on improving patient engagement in care through tools or supports (*e.g.,* free or reduced-cost technology, free local transportation services), potentially implicating both the Federal anti-kickback statute and the Beneficiary Inducements CMP. Such tools or supports may not fit easily (or at all) under existing safe harbors to the Federal anti-kickback statute or exceptions to the definition of ''remuneration'' under the Beneficiary Inducements CMP.

Public stakeholders have asserted—through comments to both the OIG RFI and OIG Proposed Rule, as well as other public forums—that this lack of clear legal protection has a chilling effect on the development of effective care coordination arrangements, value-based arrangements, and arrangements engaging or supporting patients. As a consequence, this final rule provides greater certainty and protection for care coordination arrangements, value-based arrangements, patient engagement tools and supports, and other beneficial arrangements from potential liability under the Federal anti-kickback statute and Beneficiary Inducements CMP (as applicable), if the arrangements are properly structured to satisfy an applicable safe harbor's or exception's conditions (as applicable).

2. Overview of Estimated Impact of the Final Rule

There is not enough available information to estimate this final rule's effect on the economy, Federal or State expenditures, or small providers. In other words, we are not able to provide quantitative estimates of savings to or expenditures for the Federal health care programs, providers, and others that will result from this final rule. More specifically, we lack a basis for determining the scope and magnitude of financial arrangements for which parties may seek safe harbor protection.

We lack a basis for making any quantitative estimates for the following reasons. First, we cannot estimate how many providers and other industry stakeholders will enter in value-based and care coordination arrangements or other arrangements protected by these final safe harbors and exception. This is in part because using and complying with the safe harbors and exception to the definition of ''remuneration'' under the Beneficiary Inducements CMP finalized here are voluntary. Indeed, providing remuneration in the context of a care coordination arrangement and engaging Federal health care program beneficiaries through the provision of tools and supports are voluntary as well. Stated otherwise, parties are not required either to enter into financial relationships that implicate the Federal anti-kickback statute and Beneficiary Inducements CMP, or to structure any financial relationships that implicate these statutes to satisfy a safe harbor or exception, as applicable. Failure to satisfy a safe harbor or exception, as applicable, does not mean that an arrangement is illegal under the Federal anti-kickback statute or Beneficiary Inducements CMP. Parties are free to conduct financial arrangements that do not fit within the protections set forth in these final regulations provided that they otherwise comply with the law. Further, while parties often use safe harbors and exceptions as tools to structure compliant arrangements, parties may also wait to assert compliance with a safe harbor as a defense should the Government bring an enforcement action. For this reason, it is further difficult to estimate usage of these regulations.

Second, while we can provide examples—as noted below—of arrangements we believe health care industry stakeholders may enter into under the protection of these final safe harbors and exception, we cannot predict the form of all of the arrangements, nor which industry stakeholders will enter into what form of arrangements. More specifically, based on comments submitted by stakeholders, our understanding of currently existing value-based and care coordination arrangements, and our assumption that there will be continued innovation, we expect significant heterogeneity in value-based and care coordination arrangements that seek protection under these safe harbors and exception. Applying a ''conceptual framework'' developed by RAND Corporation in an assessment of value-based programs illuminates how the attributes of value-based care and care coordination arrangements could vary across the industry, making any basis for quantitative estimates regarding the impact of the regulatory flexibilities set forth in this final rule highly speculative.[160]

In particular, the RAND conceptual framework highlights how various aspects of the arrangements for which parties may seek safe harbor and exception protection could differ, including: (1) Overarching program design features with respect to the value-based arrangement (*e.g.,* measures, incentive structure, targets for incentives, and quality improvement support and resources); (2) the characteristics of the providers and the settings in which they practice, including whether or not the providers are employees, as well as the characteristics of other parties to the arrangement; and (3) external factors (*e.g.,* other payment policies, other quality initiatives, consumer behavior, market characteristics, and regulatory changes) that can enable or hinder any response to the incentive. In addition, we expect wide variation in the patient populations served and their particular needs with respect to care coordination and tools and supports. To provide an example related to external factors, whether a provider might need to use the patient engagement and support safe harbor (paragraph 1001.952(hh)) may depend on whether the beneficiary's Federal health care program covered the desired tool and support. An arrangement for the provision of digital technology that is a covered item or service, when provided in accordance with coverage and payment rules, does not likely require safe harbor protection and additional regulatory flexibility in this final rule. On the other hand, an arrangement for the provision of noncovered tools and supports for free to a Federal health care program beneficiary likely implicates the Federal anti-kickback statute and may implicate the Beneficiary Inducements CMP, may need safe harbor protection, and would

[160] Cheryl L. Damberg et al., RAND Corp., *Measuring Success in Health Care Value-Based Purchasing Programs* (2014), *available at https://www.rand.org/content/dam/rand/pubs/research_reports/RR300/RR306/RAND_RR306.pdf.*

benefit from such flexibility. Variation in coverage and payment rules and changes in such rules over time impact the analysis of the application of the statutes to arrangements and whether parties would seek to use the final regulations.

In sum, any estimation of behavioral change—and any resulting increases or decreases in costs to Federal or State health care programs, providers and other stakeholders, or patients—would be highly speculative and too uncertain to be appropriately quantifiable. While we cannot gauge with certainty savings or costs that may result from this final rule, the rule reflects our effort to remove barriers impeding wider adoption of beneficial care coordination and value-based arrangements identified by stakeholders, while prohibiting arrangements that would improperly increase utilization, promote anti-competitive behavior, or result in fraud or abuse. Below we elaborate on the intended and anticipated beneficial outcomes related to the final rule as well as some potential costs.

3. Anticipated Outcomes of the Final Rule

We can reasonably predict, however, that the final rule likely will result in changes to stakeholder behavior. The rule may increase providers' or others' participation in beneficial value-based, care coordination, patient engagement and support, and other arrangements to the extent that providers or others have been concerned that such arrangements would otherwise implicate the Federal anti-kickback statute and Beneficiary Inducements CMP. In this regard, and with respect to the intended outcomes and benefits related to this final rule, we anticipate that the policies in this final rule may: (1) Remove barriers to robust participation in beneficial value-based health care delivery and payment systems, including those administered by CMS and non-Federal payors; (2) facilitate arrangements for beneficial patient care coordination among affiliated and unaffiliated health care providers, practitioners, suppliers, and others; (3) remove barriers to providing tools and supports to patients to better engage them in their care and improve health outcomes; (4) provide certainty for participants in the Medicare Shared Savings Program and Innovation Center models; (5) facilitate the continued adoption and use of electronic health records by making permanent the safe harbor for the donation of such items and services; and (6) promote more robust cybersecurity throughout the health care system. Some of the benefits that we anticipate will arise from these intended outcomes are: (1) Improved care coordination for patients, including Federal health care program beneficiaries; (2) improved quality of care and outcomes for patients, including Federal health care program beneficiaries; (3) potential reduction in compliance costs to individuals and entities to which the Federal anti-kickback statute's and Beneficiary Inducements CMP's prohibitions apply; (4) reduction in administrative complexity and related waste from continued progress toward interoperability of data and electronic health records; (5) protection against the corruption of or access to health records and other information essential to the safe and effective delivery of health care; and (6) reduction in impacts of cybersecurity attacks, including the improper disclosure of protected health information (PHI), and reduction in costs associated with cybersecurity attacks, including ransom payments, costs to patients whose PHI is improperly disclosed, and costs to providers, suppliers, and others to reestablish cybersecurity.

With respect to the final rule's impact on parties currently participating in the Medicare Shared Savings Program and Innovation Center models, we have determined that this Final Rule would not significantly alter the conditions upon which such providers and suppliers operate. Such parties currently must comply with the fraud and abuse statutes and receive fraud and abuse waivers as needed for CMS to operate the Medicare Shared Savings Program and test models, as authorized by statute. Finalizing safe harbors protecting value-based arrangements, care coordination, and certain patient engagement tools and supports would not significantly alter these conditions. This is particularly true in light of the new final safe harbor for CMS-sponsored models, which is designed to streamline the current fraud and abuse waiver process and make model participation more uniform with respect to compliance with fraud and abuse laws.

4. Expanded Protections Under Final Rule and Examples of Anticipated Arrangements

As explained in greater detail in the preamble above, this final rule expands safe harbor protection under the Federal anti-kickback statute to protect the following types of arrangements that, in most cases, would not fit squarely or with certainty in existing safe harbors:

- Certain remuneration exchanged between or among eligible participants in a value-based arrangement that fosters better coordinated and managed patient care.
- Certain tools and supports furnished to patients to improve quality, health outcomes, and efficiency.
- Certain remuneration provided in connection with a CMS-sponsored model.
- Certain donations of cybersecurity technology and services.
- Certain donations of electronic health records items and services.
- Certain outcomes-based payments and remuneration in connection with part-time personal services and management contracts arrangements.
- Certain remuneration in connection with bundled warranties for one or more items and related services.
- Certain free or discounted local transportation given to Federal health care program beneficiaries.

In addition, this final rule extends protection under the Beneficiary Inducements CMP to protect certain ''telehealth technologies'' furnished to certain in-home dialysis patients.

Based on the Department's experience with the Medicare Shared Savings Program and Innovation Center models, information provided by commenters on the OIG RFI and the OIG Proposed Rule, and information shared publicly by providers, suppliers, practitioners, health plans, and others, following the issuance of this final rule we reasonably expect parties may seek protection under the final safe harbors and exception such as the following:

- A hospital—in recognition that new reimbursement models may extend hospital accountability for a patient's health beyond inpatient or outpatient care—may wish to provide recently discharged patients with free health coaching, technology that facilitates remote monitoring, a non-reimbursable home visit, or nutritional supplements to promote the best health outcomes after discharge.
- A hospital, recognizing that clinical collaboration and care coordination may improve patient transitions from one care delivery point to the next, may wish to provide care coordinators that furnish individually tailored case management services for patients requiring post-acute care.
- A medical device manufacturer may wish to offer a physician practice or hospital a data analysis service to track clinical practices, clinical outcomes, and patient impact as they relate to hospital- or health-care-acquired pressure injuries.
- A hospital may wish to provide support and to reward institutional post-acute providers for achieving outcome measures that effectively and

efficiently coordinate care across care settings and reduce hospital readmissions. Such measures would be aligned with a patient's successful recovery and return to living in the community.

• A physician may wish to offer—for free— a prescription pickup service to retrieve filled prescriptions from the pharmacy and get them to the patient to expedite the patient's adherence to the physician's ordered treatment.

• A primary care physician, dialysis facility, or other provider could furnish a smart tablet that is capable of two-way, real-time interactive communication between the patient and his or her physician. In turn, the Federal health care program beneficiary's access to a smart tablet could facilitate communication through telehealth and the provision of in-home dialysis services.

5. Anticipated Beneficial Impact of Value-Based, Care Coordination, and Patient Engagement and Support Arrangements

As explained further below, to the extent that providers and others elect to use these safe harbors and exception to the definition of ''remuneration'' under the Beneficiary Inducements CMP to protect care coordination, value-based, and other arrangements, there could be significant beneficial impacts should the intended effect of the regulatory flexibilities afforded by this final rule—promoting the adoption of beneficial value-based arrangements and improved care coordination—come to fruition.

As noted above, we are unable to quantify with certainty any impact related to the changes in industry behavior that we can reasonably expect following the effective date of this final rule. Despite the inability to quantify impact, we believe that the value-based arrangements, care coordination arrangements, and patient engagement and support arrangements protected by this final rule ultimately will reduce waste in the U.S. health care system.

In particular, a recent review of literature from January 2012 to May 2019 focusing on unnecessary spending, or waste, in the U.S. health care system (the 2019 study) indicates that waste related to the failure of care coordination alone results in annual costs of $27 billion to $78 billion.[161] Much of the research on waste and improvement reviewed in the 2019 study was conducted in Medicare populations. The 2019 study noted empirical evidence that interventions, such as aligning payment models with value or supporting delivery reform to enhance care coordination, safety, and value, can produce meaningful savings and reduce waste by as much as half. The 2019 study also identified waste from administrative complexity (resulting from fragmentation in the health care system) as the greatest contributor to waste in the U.S. health care system at an estimated $266 billion annually, and highlighted the opportunity to reduce waste in this category from enhanced payor collaboration with health care providers and clinicians in the form of value-based payment models. According to the 2019 study, as value-based care continues to evolve, there is reason to believe that such interventions can be coordinated and scaled to produce better care at lower cost for all U.S. residents. Moreover, in value-based and care coordination arrangements, improvements could reduce waste related to overtreatment and low-value care, a separate category of waste in the U.S. health care system.

OIG studies regarding the Medicare Shared Savings Program and participating ACOs have found beneficial impacts through improved quality of care and reduced spending. A June 2019 evaluation found that Medicare Shared Savings Program ACOs have developed a number of strategies that the ACOs found successful in reducing Medicare spending and improving quality of care.[162] These strategies include, among others, engaging beneficiaries to improve their own health, reducing avoidable hospitalizations and improving hospital care through better care coordination, and using technology for information sharing. For example, one ACO in the study used tablets to issue medication reminders and digital scales to transmit information directly to care coordinators to help manage the health of beneficiaries with end-stage congestive heart failure. The ACO reported that hospitalizations for this group declined, on average, from four times a year to one time. The evaluation observes that the successful strategies can apply not only to ACOs but also to other providers committed to transforming the health care system toward value.

An August 2017 OIG report analyzed spending and quality data from the first 3 years of the Medicare Shared Savings Program to determine the extent to which ACOs reduced Medicare spending and improved quality.[163] During the period studied, most of the 428 participating ACOs (serving 9.7 million beneficiaries) reduced Medicare spending compared to their benchmarks, achieving a net spending reduction of nearly $1 billion. At the same time, ACOs generally improved their performance on most of the individual quality measures. ACOs also outperformed fee-for-service providers on most of the quality measures. A small subset of ACOs showed substantial reductions in Medicare spending while providing high-quality care. These high-performing ACOs reduced spending by an average of $673 per beneficiary for key Medicare services during the review period. This included significant spending reductions for high-cost services such as inpatient hospital care and skilled nursing facility care. These ACOs also maintained high use of primary care services, which can lower utilization and costs for other care, and reduced the use of costly services such as emergency department visits. In contrast, other Medicare Shared Savings Program ACOs and the national average for fee-for-service providers showed an increase in per beneficiary spending for key Medicare services.

In addition, we are aware that certain other innovative value-based and care coordination arrangements exist that have resulted in cost savings for third-party payors, quality of care improvements, or both.[164] While we cannot extrapolate these results to the possible impact of this final rule, we

[161] William H. Shrank et al., *Waste in the US Health Care System, Estimated Costs and Potential for Savings,* 322 JAMA 1501 (2019), *available at https://jamanetwork.com/journals/jama/fullarticle/2752664.*

[162] OIG, ACOs' Strategies for Transitioning to Value-Based Care: Lessons From the Medicare Shared Savings Program (OEI–02–15–00451), July 19, 2019. *Available at https://oig.hhs.gov/oei/reports/oei-02-15-00451.asp.*

[163] OIG, Medicare Shared Savings Program Accountable Care Organizations Have Shown Potential for Reducing Spending and Improving Quality (OEI–02–15–00450), Aug. 28, 2017. Available at *https://oig.hhs.gov/oei/reports/oei-02-15-00450.asp.*

[164] *See e.g.,* Brian W. Powers et al., *Impact of Complex Care Management on Spending and Utilization for High-Need, High-Cost Medicaid Patients,* 26 Am. J. Managed Care e57 (2020), *available at https://doi.org/10.37765/ajmc.2020.42402* (finding, in a study of a complex care management program implemented in Tennessee for high-need, high-cost Medicaid patients, that the program reduced total medical expenditures by 37 percent and inpatient utilization by 59 percent); Shreya Kangovi et al., *Evidence-Based Community Health Worker Program Addresses Unmet Social Needs and Generates Positive Return on Investment,* 39 Health Aff. 207 (2020), *available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.00981* (finding that every dollar invested in the Individualized Management for Patient-Centered Targets (IMPaCT) intervention, which is ''a standardized community health worker intervention that addresses socioeconomic and behavioral barriers to health in low-income populations,'' yielded a return of $2.47 within a single fiscal year from the perspective of a Medicaid payer).

believe the reported success of some of these programs suggests the promising nature of value-based care and improved care coordination. In describing the results below, we do not mean to suggest that this rule prescribes or endorses the interventions inherent to these results. Further, we emphasize that this final rule simply removes certain regulatory barriers to implementing value-based and care coordination arrangements that may be similar to those described below.

For example, a case study targeted at determining the specific factors that reduce Medicare payments and lead to hospital savings in bundled payment models for lower extremity joint replacement surgeries (which provide a lump sum payment to be shared among providers for an episode of care instead of payment for every service performed) in one Texas health system found that, between July 2008 and June 2015, the system's five hospitals were able to reduce total Medicare spending per episode of care by $5,577, or 20.8 percent, in cases without complications, and by $5,321, or 13.8 percent, in cases with complications.[165] The hospitals also recognized $6.1 million in internal cost savings, along with slight decreases in emergency room visits and readmission rates, and a decrease in cases with a prolonged length-of-stay admission. Over half of the internal cost savings were attributable to reduced implant costs.[166] We note that the product standardization incentive programs that contribute to such internal cost savings involve compensation arrangements between hospitals and physicians which, depending on their structure, may not satisfy the requirements of any current safe harbors to the Federal anti-kickback statute, but to which the new and modified safe harbors may apply. Relatedly, in 2018, a large health plan announced that it was expanding a bundled payment program for spinal surgeries and hip/knee replacements to new markets, after finding savings of $18,000 per procedure,[167] and a health network reported over $10 million in savings in 2017 with more anticipated savings in 2018.[168]

As another example of the potential for cost savings associated with value-based arrangements, a recent survey of more than 100 commercial payors showed that, in 2018, ''pure FFS'' payment—where each medical service is billed and paid for separately—accounts for only 37.2 percent of reimbursement and is expected to drop to 26 percent by 2021.[169] According to the payors surveyed, payors that adopted value-based health care delivery and payment models reduced health care costs by an average of 5.6 percent, improved provider collaboration, and created more impactful member engagement.

Further, there are studies that suggest that improved care coordination may decrease costs and enhance health outcomes. One randomized, controlled trial evaluated the cost-effectiveness of a home-based care coordination program that targeted older adults with problems self-managing their chronic illnesses.[170] Study participants in the test group received care coordination services from a nurse and a pill organizer. The results of this study showed that, for those beneficiaries who participated in the study for more than 3 months, total Medicare costs were $491 lower per month than in the control group. Another study conducted by the Centers for Disease Control and Prevention demonstrated that certain interventions, such as team-based or coordinated care, increase patient medication adherence rates.[171] Specifically, in a 2015 study, patients assigned to team-based care—including pharmacist-led medication reconciliation and tailoring, pharmacist-led patient education, collaborative care between pharmacist and primary care provider or cardiologist, and two types of voice messaging—were significantly more adherent with their medication regimen 12 months after hospital discharge (89 percent) compared with patients not receiving team-based care (74 percent).

In addition, there are reported examples of value-based health care delivery and payment programs developed and implemented by commercial health plans that report success. For example, one health plan recently reported that it saved $1 billion through avoided costs in 3 years of its recent primary care pay-for-value program that offers primary care practices rewards for their performance on quality, cost, and utilization measures, while also improving outcomes for the plan's members.[172] According to this plan, members treated by a primary care provider in the program had 11 percent fewer emergency room visits in 2017 than members treated by a primary care physician not in the program. The plan also stated that members with a primary care physician in the program experienced 16 percent fewer inpatient admissions in 2017 compared to members seeing a primary care physician not in the program, potentially saving the plan $224 million in inpatient care costs.[173]

A collaboration between a physician-led ACO and a health plan in North Carolina similarly reportedly reduced costs while improving quality of care.[174] Specifically, an analysis conducted by the plan concluded that the 47 primary care practices that participated in the collaboration: (1) Reduced the total cost of care by 4.7 percent for commercial patients; (2) reduced the total cost of care by 6.1 percent for Medicare Advantage patients; and (3) improved their Medicare star ratings, on average, from 3 to 4.5 stars. Another analysis by a different health plan determined that primary care physicians paid under global capitation improved certain patient outcomes related to preventive care and chronic conditions, such as

[165] Amol S. Navathe, *et al., Cost of Joint Replacement Using Bundled Payment Models,* 177(2) JAMA Internal Med. 214–222 (Feb. 2017), *available at https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2594805.*

[166] Vera Gruessner, *3 Ways Bundled Payment Models Brought Hospital Cost Savings,* Health Payer Intelligence (Jan. 16, 2017), *https://healthpayerintelligence.com/news/3-ways-bundled-payment-models-brought-hospital-cost-savings.*

[167] David Muhlestein et al., *Recent Progress In The Value Journey: Growth Of ACOs And Value-Based Payment Models In 2018,* Health Affairs Blog (Aug. 14, 2018), *https://www.healthaffairs.org/do/10.1377/hblog20180810.481968/full/.*

[168] Shane Wolverton, *Providers partner with payers for bundled payments,* Becker's Payer Issues (May 10, 2018) *https://www.beckershospitalreview.com/payer-issues/providers-partner-with-payers-for-bundled-payments.html.*

[169] Thomas Beaton, *Value-Based Payment Adoption Drives 5.6% Reduction in Care Costs,* Health Payer Intelligence (June 18, 2018), *https://healthpayerintelligence.com/news/value-based-payment-adoption-drives-5.6-reduction-in-care-costs.*

[170] Karen Dorman Marek et al., *Cost analysis of a home-based nurse care coordination program,* 62 J. Am. Geriatrics Soc'y 2369 (2014).

[171] Andrea B. Neiman et al., *CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management—Innovations and Opportunities,* 66 Morbidity & Mortality Wkly. Rep. 1248 (2017), *available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm.*

[172] Press Release, Highmark, Inc., *Highmark saves more than $1 billion in avoided cost with True Performance program* (Oct. 5, 2020), *available at https://www.highmark.com/newsroom/press-releases.html#!release/highmark-saves-more-than-1-billion-in-avoided-cost-with-true-performance-program.*

[173] Press Release, Highmark, Inc., *Highmark's True Performance Program Avoided Health Care Costs by More Than $260 Million in 2017* (June 26, 2018), *available at https://www.highmark.com/newsroom/press-releases.html#!release/highmarks-true-performance-program-avoided-health-care-costs-by-more-than-260-million-in-2017.*

[174] Press Release, *Blue Cross and Blue Shield of North Carolina, Primary Care ACOs from Blue Cross NC and Aledade Show Significant Savings and Quality Improvements* (July 20, 2020), *available at https://mediacenter.bcbsnc.com/news/primary-care-acos-from-blue-cross-nc-and-aledade-show-significant-savings-and-quality-improvements.*

higher screening rates for colorectal and breast cancer, higher rates of medication review, and higher controlled blood sugar levels.[175]

6. Anticipated Beneficial Impact of New Safe Harbor for Cybersecurity Technology and Services

The health care sector is among the most targeted industries for cyberattacks and is also under-resourced to prevent such attacks and data breaches. As a result, the cost of cybersecurity attacks and breaches within the health care industry is significant. A study estimated that data breaches may have cost U.S hospitals $6.2 billion between 2015 and 2016.[176] Additionally, other estimates indicate that a health care organization that is breached faces $8 million dollars in costs on average as a result of the breach, or $400 per patient record involved.[177] The impact of cyberattacks extends beyond increased and unnecessary recovery and ransom costs. It may limit patient access to a provider or directly affect patient care. For example, a September 2020 cyberattack on a large health care system in the United States reportedly affected nearly 400 facilities, causing hospitals to divert ambulances during the initial stages of the attack. In addition, staff reported that some lab test results were delayed. The system responded by suspending user access to its information technology applications related to operations across the United States, requiring the use of backup processes, including paper medical record charting and labeling medications by hand, for nearly 3 weeks.[178]

According to the Health Sector Cybersecurity Coordination Center (HC3), health care organizations should consider implementing strong risk management practices to help prevent data breaches and minimize any disruptions or loss if a breach occurs.[179] HC3 highlights that adequate prevention and preparation for data breaches will protect patients, minimize direct and indirect costs, and allow for more efficient operations of a health care organization.[180] Separately, the HCIC Task Force's June 2017 report, among other things, highlighted its review of many concerns related to potential constraints imposed by the physician self-referral law and the Federal anti-kickback statute. The report encouraged Congress to evaluate an amendment to these laws specifically for cybersecurity software that would allow health care organizations the ability to assist physicians in the acquisition of this technology, through either donation or subsidy.[181] The HCIC Task Force noted that the existing regulatory exception to the physician self-referral law (42 CFR 411.357(w)) and the safe harbor to the Federal anti-kickback statute (42 CFR 1001.952(y)) applicable to certain donations of EHR items and services could serve as an ideal template for an analogous cybersecurity provision.[182]

Further substantiating the need for increased flexibility related to the donation of cybersecurity technology and services, in 2018, the American Medical Association surveyed over 1,300 physicians in a cybersecurity-related survey. Approximately 83 percent of the participants reported having experienced some sort of cybersecurity attack.[183] The study also highlighted that 50 percent of the surveyed physicians wished they could receive donations of security-related hardware and software from other providers, and recommended that OIG develop a safe harbor to permit it.

As described in section III.B.8 of this final rule, we received overwhelming support from across the health care industry in response to our proposal to establish the new safe harbor for cybersecurity items and services, and we anticipate significant expansion of cybersecurity efforts through donations following the effective date of this final rule, similar to the expanded adoption of EHR items and services reported by stakeholders following the establishment of the EHR safe harbor in 2006. Support for the new cybersecurity safe harbor came from many well-resourced organizations that are potential future donors of cybersecurity technology, such as health plans and large health systems, as well as from likely recipients of donations and trade groups representing practitioners.

Because of the cost of cybersecurity attacks to organizations that wish to donate or receive cybersecurity technology and services, and the general support among donors and recipients for the new cybersecurity exception, we anticipate significant investment in improvements to the cybersecurity hygiene of the health care industry. An organization's cybersecurity posture is only as strong as its weakest link, including weaknesses of downstream providers, suppliers, and practitioners that wish to receive donations; thus, donors are incented to protect themselves by donating cybersecurity technology and services that improves their cybersecurity.

There are a variety of factors integral to determining the impact of this final safe harbor's effect on the cybersecurity hygiene of the health care industry that remain too speculative to make a quantitative estimate of the impact of this final rule. We cannot predict with sufficient certainty various elements that will determine the impact of this safe harbor. For example, we cannot predict: (1) How many health care industry stakeholders will donate cybersecurity technology or services for which parties may seek safe harbor protection; (2) the specific combinations of items and services that will be donated or how such donations will improve the cybersecurity hygiene of recipients, donors, and the health care industry as a whole; and (3) external factors (*e.g.,* other policies promoting cybersecurity within the health care industry, how cyber criminals will proliferate and develop new strategies, how cyberattack recovery costs and ransom costs will change) that can enable or hinder improved cybersecurity hygiene and potentially

[175] UnitedHealth Group, Physicians Provide Higher Quality Care Under Set Monthly Payments Instead of Being Paid Per Service, UnitedHealth Group Study Shows (Aug. 11, 2020), *available at https://www.unitedhealthgroup.com/newsroom/2020/uhg-study-shows-higher-quality-care-under-set-monthly-payments-403552.html.*

[176] Ponemon Institute, *Sixth Annual Benchmark Study on Privacy & Security of Healthcare Data* (May 2016), *available at https://www.ponemon.org/local/upload/file/Sixth%20Annual%20Patient%20Privacy%20%26%20Data%20Security%20Report%20FINAL%206.pdf.*

[177] Health Sector Cybersecurity Coordination Center, *A Cost Analysis of Healthcare Sector Data Breaches* (Apr. 4, 2019), *available at https://www.hhs.gov/sites/default/files/cost-analysis-of-healthcare-sector-data-breaches.pdf.*

[178] Jeff Lagasse, *Universal Health Services hit with cyberattack that shuts down IT systems,* Healthcare Finance (Sept. 29, 2020), *https://www.healthcarefinancenews.com/news/universal-health-services-hit-cyberattack-shuts-down-it-systems-1*; Jessica Davis, *UPDATE: UHS Health System Confirms All US Sites Affected by Ransomware Attack*, Health IT Security (Oct. 5, 2020) *https://healthitsecurity.com/news/uhs-health-system-confirms-all-us-sites-affected-by-ransomware-attack*; Jessica Davis, *3 Weeks After Ransomware Attack, All 400 UHS Systems Back Online,* Health IT Security (Oct. 13, 2020), *https://healthitsecurity.com/news/3-weeks-after-ransomware-attack-all-400-uhs-systems-back-online*; and Press Release, Universal Health Services (Oct. 29. 2020), *https://www.uhsinc.com/statement-from-universal-health-services/.*

[179] Health Sector Cybersecurity Coordination Center, *A Cost Analysis of Healthcare Sector Data Breaches* (Apr. 4, 2019), *https://www.hhs.gov/sites/default/files/cost-analysis-of-healthcare-sector-data-breaches.pdf.*

[180] *Id.*

[181] HCIC Task Force Report, *https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.*

[182] *Id.*

[183] American Medical Association, *Tackling Cyber Threats in Healthcare, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/medical-cybersecurity-findings.pdf* and *https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/infographic-medical-cybersecurity.pdf.*

result in increased or decreased costs associated with cyberattacks. Despite this, we expect that the flexibility to donate cybersecurity technology and services will benefit the ecosystem as a whole, improve cybersecurity across the industry, and reduce costs associated with cyberattacks (by improving prevention and detection of cybersecurity weaknesses and reducing successful cyberattacks, and consequently, ransom fees and recovery costs). However, we cannot predict the specific impacts of the flexibility afforded by the cybersecurity technology and services safe harbor on the costs or benefits to Federal health care programs, beneficiaries, or the health care industry as a whole.

7. Anticipated Costs

We also acknowledge that there could be some costs associated with this final rule. For example, providers and other stakeholders voluntarily complying with the safe harbors and exception finalized here may incur legal and administrative costs to appropriately structure an arrangement to satisfy an applicable safe harbor or exception. In addition, it is possible providers and others may misuse the protection afforded by the safe harbors and exception which could result in increased costs to Federal health care programs or beneficiaries. It also is possible that providers and other stakeholders will appropriately use the safe harbors, but a care coordination or value-based arrangement developed in good faith might not result in savings to the Federal health care programs or beneficiaries or improvements in quality of care.

Designing safe harbors with sufficient safeguards against potential abuses and harms by those who might misuse the safe harbors is not without challenges. In this final rule, we have tried to strike the right balance between flexibility for beneficial innovation and safeguards to protect patients and Federal health care programs. However, we cannot quantify whether we have struck the appropriate balance; in particular, we cannot quantify whether achievement of the intended outcomes (*e.g.,* improved coordination of patient care, improved quality of patient care, reduced costs to payers) will outweigh any potential costs.

B. Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects (*i.e.,* $100 million or more in any given year). This final rule codifies a new exception to the definition of ''remuneration'' under the Beneficiary Inducements CMP and implements new or revised anti-kickback statute safe harbors. As explained more fully above, we believe the changes in the final rule to the safe harbors and the new exception to the Beneficiary Inducements CMP will provide flexibility for providers and others to enter into certain beneficial arrangements. In doing so, this final rule imposes no requirements on any party. Providers and others will be allowed to voluntarily seek to comply with these provisions so that they have assurance that participating in certain arrangements will not subject them to liability under the Federal anti-kickback statute and the Beneficiary Inducements CMP. These safe harbors and exception facilitate providers' and others' ability to provide important health care and related services to communities in need. We estimated that this rule would be ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that presented our estimates of the costs and benefits of this rulemaking. Thus, this rule has been reviewed by the Office of Management and Budget.

C. Regulatory Flexibility Act

The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and Government agencies. Most providers are considered small entities by having revenues of $7 million to $35.5 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered small entities.

Comment: We received comments from two associations representing small and rural providers or Indian health care providers regarding the level of administrative burden and potential costs associated with implementing the requirements in certain proposed safe harbors (*e.g.,* requiring a writing signed by the parties under certain proposed safe harbors and requiring a financial contribution by a recipient of remuneration under the care coordination arrangements safe harbor and EHR safe harbor), particularly for small and rural providers and Indian health care providers. For example, a commenter suggested that if OIG reduced administrative burden on physicians under its final rule, it would allow physicians to focus on the patient-physician relationship and the patient's welfare. In addition, a commenter representing Indian health care providers expressed concern that its stakeholders would need to make changes to current practices and operations in response to this rulemaking in order to comply with the Federal anti-kickback statute and to avoid severe criminal, civil, and administrative penalties. The commenter also raised concerns regarding potential administrative burden that may occur if Indian health care providers revise or amend existing agreements with the Health Resources and Services Administration to participate in arrangements protected under new safe harbors. The commenter also asked OIG to exempt Indian health programs from certain proposed safe harbor contribution requirements.

Response: We reiterate that this final rule does not impose any obligations on any entity, including Indian health care providers, nor does this final rule require any entity to make changes to current practices and operations to comply with the Federal anti-kickback statute or Beneficiary Inducements CMP. This final rule provides additional flexibilities for providers and others to enter into care coordination arrangements with potentially reduced legal risk. As explained above, structuring financial arrangements to satisfy a safe harbor or exception is voluntary; indeed, even entering into such financial arrangements is voluntary. We believe the changes to the safe harbors and the addition of a new exception to the definition of ''remuneration'' under the Beneficiary Inducements CMP provide industry stakeholders with additional flexibility if they desire to enter into certain beneficial arrangements.

We understand the commenter's concern regarding potential costs associated with contribution requirements included within certain safe harbors that we are finalizing. However, after careful consideration, we continue to believe that the contribution requirement is an important safeguard against fraud and abuse in light of the specific risks of inappropriate generation of referrals presented by donations of EHR items and services that could be protected by the EHR safe harbor(paragraph 1001.952(y)) and care

coordination arrangements safe harbor (paragraph 1001.952(ee)). As we explain in our discussion of these safe harbors in sections III.B.3.g and III.B.9.e above, when recipients of valuable remuneration have some responsibility to contribute to the cost of the items or services, they are more likely to make economically prudent decisions and accept only what they need or will use. The final rule reflects our efforts to balance additional flexibility for beneficial arrangements that have potential to reduce costs and improve care with safeguards to protect against potential abuses, including inappropriate increases in costs to Federal health care programs and beneficiaries.

We recognize that small or rural entities or Indian health care providers may incur costs to avail themselves of the safe harbor and exception protections under the final rule. However, we expect the costs to be no greater than parties currently incur to comply with the Federal anti-kickback statute and the Beneficiary Inducements CMP. We do not expect this final rule to have a significant impact on a substantial number of small entities or Indian health care providers because the rules are completely voluntary (*i.e.,* providers are not required to comply with the conditions of any safe harbor in order to avoid violating the Federal anti-kickback statute). Furthermore, we believe the net impact on small businesses that choose to take advantage of the new flexibilities will be low because we anticipate that the potential burden associated with certain provisions may be mitigated by other provisions offering greater flexibility to providers.

We estimate the changes to the exception to the Beneficiary Inducements CMP and the Federal anti-kickback statute safe harbors will impose no incremental burden on covered entities. We are providing covered entities with the option to adjust their business practices to better serve patients without adversely affecting their profitability. As a result, we have concluded that this final rule likely will not have a significant impact on a substantial number of small providers and that a regulatory flexibility analysis is not required for this rulemaking. In addition, section 1102(b) of the Act requires that we prepare a regulatory impact analysis if a rule under titles XVIII or XIX or section B of title XI of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. For the reasons stated above, we do not believe that any provisions or changes finalized here will have a significant impact on the operations of rural hospitals. Thus, an analysis under section 1102(b) of the Act is not required for this rulemaking.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State Governments, Tribal Governments, or local governments, in the aggregate, or by the private sector, of $100 million, adjusted for inflation. We believe that no significant costs will be associated with this final rule that would impose any mandates on State Governments, Tribal Governments, local governments, or the private sector that would result in an expenditure of $154 million (after adjustment for inflation) in any given year.

D. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements for costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this final rule will not significantly affect the rights, roles, and responsibilities of State or local governments.

E. Executive Order 13771

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule has been designated a significant regulatory action as defined by Executive Order 12866 but imposes no more than *de minimis* costs and is a deregulatory action under Executive Order 13771. This designation has been informed by public comments.

F. Statement of Need

The Department has identified the broad reach of the Federal anti-kickback statute and Beneficiary Inducements CMP as potentially inhibiting beneficial arrangements that would advance the ability of providers, suppliers, and others to transition more effectively and efficiently to value-based care and to better coordinate care among providers, suppliers, and others in both the Federal health care programs and commercial sectors. Industry stakeholders have informed us that, because the consequences of potential noncompliance with the Federal anti-kickback statute and Beneficiary Inducements CMP could be significant, providers, suppliers, and others may be discouraged from entering into innovative arrangements that could improve quality outcomes, produce health system efficiencies, and lower health care costs (or slow their rate of growth). To the extent providers are discouraged from entering into these innovative arrangements, patient care may not be provided as efficiently as possible. In addition, the potential consequences of noncompliance with these statutes may impede the ability of providers, suppliers, and others, including small providers and suppliers or those serving rural or medically underserved populations, to raise capital to invest in the transition to value-based care or to obtain infrastructure necessary to coordinate patient care, including technology. This unnecessarily slows the transition toward more efficient patient care. This final rule attempts to address these concerns by removing unnecessary impediments to the transformation of the health care system into one that better pays for and delivers value.

To remove regulatory barriers to care coordination and support value-based arrangements, we faced the challenge of designing safe harbor protections for emerging health care arrangements, the optimal form, design, and efficacy of which remain unknown or unproven. These arrangements will be driven by the determinations and experiences of a wide range of providers, suppliers, and others as they innovate in delivering value-based care. This challenge is further complicated by the substantial variation in care coordination and value-based arrangements contemplated by the health care industry and others (meaning that one-size-fits-all safe harbor designs may not be optimal), variation among patient populations and provider characteristics, emerging health technologies and data capabilities, the still-developing science of quality and performance measurement, and our desire not to have a chilling effect on beneficial innovations.

As described above, it is difficult to gauge the effects of this regulatory action in a rapidly evolving and diverse health care ecosystem of substantial innovation, experimentation, and deployment of technology and digital data. For example, as explained above, while a recent article projected potential savings of $29.6 billion to $38.2 billion across the U.S. health care system for

reducing waste from failure of care coordination,[184] it is difficult, if not impossible to gauge reductions in wasteful health care spending and improved health outcomes as a result of new arrangements made possible by this final rule. It is also difficult, if not impossible, to quantify savings or losses that could occur as a result of new fraudulent or abusive conduct that could increase costs or lead to poor outcomes as a result of new arrangements. In some cases, innovations may enhance program integrity and protect against fraud and abuse, reducing costs and increasing benefits. There is a compelling concern that uncertainty and regulatory barriers under current regulations could prevent the best and most efficacious innovations from emerging and being tested in the marketplace. Our goal in finalizing safe harbors is to protect arrangements that foster beneficial arrangements and facilitate value, while also protecting programs and beneficiaries against harms cause by fraud and abuse.

VI. Paperwork Reduction Act

The provisions of this final rule will not impose any new information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

List of Subjects

42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Social Security.

42 CFR Part 1003

Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting, and recordkeeping.

For the reasons set forth in the preamble, the Office of Inspector General, Department of Health and Human Services, amends 42 CFR parts 1001 and 1003 as follows:

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEATH PROGRAMS

■ 1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7a, 1320a–7b, 1320a–7d, 1395u(j), 1395u(k), 1395w–104(e)(6), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

■ 2. Section 1001.952 is amended by:
■ a. Revising paragraphs (d), (g) introductory text, (g)(1), (3), and (4);
■ b. Adding paragraphs (g)(5) and (g)(6) before the undesignated text at the end of paragraph (g);
■ c. Designating the undesignated text at the end of paragraph (g) as paragraph (g)(7) and revising newly redesignated (g)(7);
■ d. Revising paragraph (y) introductory text, paragraph (y)(1), the second sentence of paragraph (y)(2);
■ e. Removing and reserving paragraphs (y)(3) and (7);
■ f. Revising paragraph (y)(11);
■ g. Removing and reserving paragraph (y)(13);
■ h. Redesignating the note to paragraph (y) as paragraph (y)(14) and revising newly redesignated (y)(14);
■ i. Revising paragraphs (bb)(1)(iv)(B) and (bb)(2)(iii);
■ j. Redesignating the note to paragraph (bb) as paragraph (bb)(3) and revising newly redesignated (bb)(3);
■ k. Adding and reserving paragraphs (cc) and (dd); and
■ l. Adding paragraphs (ee) through (kk).

The revisions and additions read as follows:

§ 1001.952 Exceptions.

* * * * *

(d) *Personal services and management contracts and outcomes-based payment arrangements.* (1) As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following standards are met:

(i) The agency agreement is set out in writing and signed by the parties.

(ii) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

(iii) The term of the agreement is not less than 1 year.

(iv) The methodology for determining the compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

(v) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(vi) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

(2) As used in section 1128B of the Act, ''remuneration'' does not include any outcomes-based payment as long as all of the standards in paragraphs (d)(2)(i) through (viii) of this section are met:

(i) To receive an outcomes-based payment, the agent achieves one or more legitimate outcome measures that:

(A) Are selected based on clinical evidence or credible medical support; and

(B) Have benchmarks that are used to quantify:

(*1*) Improvements in, or the maintenance of improvements in, the quality of patient care;

(*2*) A material reduction in costs to or growth in expenditures of payors while maintaining or improving quality of care for patients; or

(*3*) Both.

(ii) The methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of the agreement is: Set in advance; commercially reasonable; consistent with fair market value; and not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part by a Federal health care program.

(iii) The agreement between the parties is set out in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the terms of the outcomes-based payment arrangement. The writing states at a minimum: A general description of the services to be performed by the parties for the term of the agreement; the outcome measure(s) the agent must achieve to receive an outcomes-based payment; the clinical evidence or credible medical support relied upon by the parties to select the outcome measure(s); and the schedule for the parties to regularly monitor and assess the outcome measure(s).

(iv) The agreement neither limits any party's ability to make decisions in their patients' best interest nor induces any party to reduce or limit medically necessary items or services.

[184] William H. Shrank et al., *Waste in the US Health Care System, Estimated Costs and Potential for Savings,* 322 JAMA 1501 (2019), available at *https://jamanetwork.com/journals/jama/article-abstract/2752664.*

(v) The term of the agreement is not less than 1 year.

(vi) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(vii) For each outcome measure under the agreement, the parties:

(A) Regularly monitor and assess the agent's performance, including the impact of the outcomes-based payment arrangement on patient quality of care; and

(B) Periodically assess, and as necessary revise, benchmarks and remuneration under the arrangement to ensure that the remuneration is consistent with fair market value in an arm's length transaction as required by paragraph (d)(2)(ii) of this section during the term of the agreement.

(viii) The principal has policies and procedures to promptly address and correct identified material performance failures or material deficiencies in quality of care resulting from the outcomes-based payment arrangement.

(3) For purposes of this paragraph (d):

(i) An agent of a principal is any person other than a *bona fide* employee of the principal who has an agreement to perform services for or on behalf of the principal.

(ii) Outcomes-based payments are limited to payments between or among a principal and an agent that:

(A) Reward the agent for successfully achieving an outcome measure described in paragraph (d)(2)(i) of this section; or

(B) Recoup from or reduce payment to an agent for failure to achieve an outcome measure described in paragraph (d)(2)(i) of this section.

(iii) Outcomes-based payments exclude any payments:

(A) Made directly or indirectly by the following entities:

(*1*) A pharmaceutical manufacturer, distributor, or wholesaler;

(*2*) A pharmacy benefit manager;

(*3*) A laboratory company;

(*4*) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(*5*) A manufacturer of a device or medical supply as defined in paragraph (ee)(14)(iv) of this section;

(*6*) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supply, as defined in paragraph (ee)(14)(iv) of this section; or

(*7*) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

(B) Related solely to the achievement of internal cost savings for the principal; or

(C) Based solely on patient satisfaction or patient convenience measures.

* * * * *

(g) *Warranties.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of one or more items and services (provided the warranty covers at least one item) to the buyer (such as a health care provider or beneficiary) of the items and services, as long as the buyer complies with all of the following standards in paragraphs (g)(1) and (2) of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) through (6) of this section:

(1) The buyer (unless the buyer is a Federal health care program beneficiary) must fully and accurately report any price reduction of an item or service (including a free item or service) that was obtained as part of the warranty in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.

* * * * *

(3) The manufacturer or supplier must comply with either of the following standards:

(i) The manufacturer or supplier must fully and accurately report any price reduction of an item or service (including free items and services) that the buyer obtained as part of the warranty on the invoice or statement submitted to the buyer and inform the buyer of its obligations under paragraphs (g)(1) and (2) of this section.

(ii) When the amount of any price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and when any price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

(4) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty.

(5) If a manufacturer or supplier offers a warranty for more than one item or one or more items and related services, the federally reimbursable items and services subject to the warranty must be reimbursed by the same Federal health care program and in the same Federal health care program payment.

(6) The manufacturer or supplier must not condition a warranty on a buyer's exclusive use of, or a minimum purchase of, any of the manufacturer's or supplier's items or services.

(7) For purposes of this paragraph (g), the term *warranty* means:

(i) Any written affirmation of fact or written promise made in connection with the sale of an item or bundle of items, or services in combination with one or more related items, by a manufacturer or supplier to a buyer, which affirmation of fact or written promise relates to the nature of the quality of workmanship and affirms or promises that such quality or workmanship is defect free or will meet a specified level of performance over a specified period of time;

(ii) Any undertaking in writing in connection with the sale by a manufacturer or supplier of an item or bundle of items, or services in combination with one or more related items, to refund, repair, replace, or take other remedial action with respect to such item or bundle of items in the event that such item or bundle of items, or services in combination with one or more related items, fails to meet the specifications set forth in the undertaking which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a seller and a buyer for purposes other than resell of such item or bundle of items; or

(iii) A manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item or bundle of items (which is covered by an agreement made in accordance with this paragraph (g)), on terms equal to the agreement that it replaces.

* * * * *

(y) *Electronic health records items and services.* As used in section 1128B of the Act, ''remuneration'' does not include nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the conditions in paragraphs (y)(1) through (13) of this section are met:

(1) The items and services are provided to an individual or entity

engaged in the delivery of health care by:

(i) An individual or entity, other than a laboratory company, that:

(A) Provides services covered by a Federal health care program and submits claims or requests for payment, either directly or through reassignment, to the Federal health care program; or

(B) Is comprised of the types of individuals or entities in paragraph (y)(1)(i)(A) of this section; or

(ii) A health plan.

(2) * * * For purposes of this paragraph (y)(2) of this section, software is deemed to be interoperable if, on the date it is provided to the recipient, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to certification criteria identified in the then-applicable version of 45 CFR part 170.

* * * * *

(11) The recipient pays 15 percent of the donor's cost for the items and services. The following conditions apply to such contribution:

(i) If the donation is the initial donation of EHR items and services, or the replacement of part or all of an existing system of EHR items and services, the recipient must pay 15 percent of the donor's cost before receiving the items and services. The contribution for updates to previously donated EHR items and services need not be paid in advance of receiving the update; and

(ii) The donor (or any affiliated individual or entity) does not finance the recipient's payment or loan funds to be used by the recipient to pay for the items and services.

* * * * *

(14) For purposes of this paragraph (y), the following definitions apply:

(i) *Cybersecurity* means the process of protecting information by preventing, detecting, and responding to cyberattacks.

(ii) *Health plan* shall have the meaning set forth at § 1001.952(l)(2).

(iii) *Interoperable* shall mean able to:

(A) Securely exchange data with and use data from other health information technology; and

(B) Allow for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law.

(iv) *Electronic health record* shall mean a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

* * * * *

(bb) * * *

(1) * * *

(iv) * * *

(B) Within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 75 miles if the patient resides in a rural area, as defined in this paragraph (bb) except that, if the patient is discharged from an inpatient facility following inpatient admission or released from a hospital after being placed in observation status for at least 24 hours and transported to the patient's residence, or another residence of the patient's choice, the mileage limits in this paragraph (bb)(1)(iv)(B) shall not apply; and

* * * * *

(2) * * *

(iii) The eligible entity makes the shuttle service available only within the eligible entity's local area, meaning there are no more than 25 miles from any stop on the route to any stop at a location where health care items or services are provided, except that if a stop on the route is in a rural area, the distance may be up to 75 miles between that stop and any providers or suppliers on the route;

* * * * *

(3) For purposes of this paragraph (bb), the following definitions apply:

(i) An *eligible entity* is any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items.

(ii) An *established patient* is a person who has selected and initiated contact to schedule an appointment with a provider or supplier, or who previously has attended an appointment with the provider or supplier.

(iii) A *shuttle service* is a vehicle that runs on a set route, on a set schedule.

(iv) A *rural area* is an area that is not an urban area, as defined in paragraph (bb)(3)(v) of this section.

(v) An *urban area* is:

(A) A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or

(B) The following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

(cc)–(dd) [Reserved]

(ee) *Care coordination arrangements to improve quality, health outcomes, and efficiency.* As used in section 1128B of the Act, ''remuneration'' does not include the exchange of anything of value between a VBE and VBE participant or between VBE participants pursuant to a value-based arrangement if all of the standards in paragraphs (ee)(1) through (13) of this section are met:

(1) The remuneration exchanged:

(i) Is in-kind;

(ii) Is used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population and does not result in more than incidental benefits to persons outside of the target patient population; and

(iii) Is not exchanged or used:

(A) More than incidentally for the recipient's billing or financial management services; or

(B) For the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

(2) The value-based arrangement is commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE.

(3) The terms of the value-based arrangement are set forth in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the value-based arrangement and any material change to the value-based arrangement. The writing states at a minimum:

(i) The value-based purpose(s) of the value-based activities provided for in the value-based arrangement;

(ii) The value-based activities to be undertaken by the parties to the value-based arrangement;

(iii) The term of the value-based arrangement;

(iv) The target patient population;

(v) A description of the remuneration;

(vi) Either the offeror's cost for the remuneration and the reasonable accounting methodology used by the offeror to determine its cost, or the fair market value of the remuneration;

(vii) The percentage and amount contributed by the recipient;

(viii) If applicable, the frequency of the recipient's contribution payments for ongoing costs; and

(ix) The outcome or process measure(s) against which the recipient will be measured.

(4) The parties to the value-based arrangement establish one or more legitimate outcome or process measures that:

(i) The parties reasonably anticipate will advance the coordination and

management of care for the target patient population based on clinical evidence or credible medical or health sciences support;

(ii) Include one or more benchmarks that are related to improving or maintaining improvements in the coordination and management of care for the target patient population;

(iii) Are monitored, periodically assessed, and prospectively revised as necessary to ensure that the measure and its benchmark continue to advance the coordination and management of care of the target patient population;

(iv) Relate to the remuneration exchanged under the value-based arrangement; and

(v) Are not based solely on patient satisfaction or patient convenience.

(5) The offeror of the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

(6) The recipient pays at least 15 percent of the offeror's cost for the remuneration, using any reasonable accounting methodology, or the fair market value of the in-kind remuneration. If it is a one-time cost, the recipient makes such contribution in advance of receiving the in-kind remuneration. If it is an ongoing cost, the recipient makes such contribution at reasonable, regular intervals.

(7) The value-based arrangement does not:

(i) Limit the VBE participant's ability to make decisions in the best interests of its patients;

(ii) Direct or restrict referrals to a particular provider, practitioner, or supplier if:

(A) A patient expresses a preference for a different practitioner, provider, or supplier;

(B) The patient's payor determines the provider, practitioner, or supplier; or

(C) Such direction or restriction is contrary to applicable law under titles XVIII and XIX of the Act; or

(iii) Induce parties to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient.

(8) The exchange of remuneration by a limited technology participant and another VBE participant or the VBE must not be conditioned on any recipient's exclusive use or minimum purchase of any item or service manufactured, distributed, or sold by the limited technology participant.

(9) The VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person reasonably monitors and assesses the following and reports the monitoring and assessment of the following to the VBE's accountable body or responsible person, as applicable, no less frequently than annually or at least once during the term of the value-based arrangement for arrangements with terms of less than 1 year:

(i) The coordination and management of care for the target patient population in the value-based arrangement;

(ii) Any deficiencies in the delivery of quality care under the value-based arrangement; and

(iii) Progress toward achieving the legitimate outcome or process measure(s) in the value-based arrangement.

(10) If the VBE's accountable body or responsible person determines, based on the monitoring and assessment conducted pursuant to paragraph (ee)(9) of this section, that the value-based arrangement has resulted in material deficiencies in quality of care or is unlikely to further the coordination and management of care for the target patient population, the parties must within 60 days either:

(i) Terminate the arrangement; or

(ii) Develop and implement a corrective action plan designed to remedy the deficiencies within 120 days, and if the corrective action plan fails to remedy the deficiencies within 120 days, terminate the value-based arrangement.

(11) The offeror does not and should not know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose.

(12) For a period of at least 6 years, the VBE or VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this paragraph (ee).

(13) The remuneration is not exchanged by:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) Except to the extent the entity is a limited technology participant, a manufacturer of a device or medical supply;

(vi) Except to the extent the entity or individual is a limited technology participant, an entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

(14) For purposes of this paragraph (ee), the following definitions apply:

(i) *Coordination and management of care (or coordinating and managing care)* means the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.

(ii) *Digital health technology* means hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care; such term includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose.

(iii) *Limited technology participant* means a VBE participant that exchanges digital health technology with another VBE participant or a VBE and that is:

(A) A manufacturer of a device or medical supply, but not including a manufacturer of a device or medical supply that was obligated under 42 CFR 403.906 to report one or more ownership or investment interests held by a physician or an immediate family member during the preceding calendar year, or that reasonably anticipates that it will be obligated to report one or more ownership or investment interests held by a physician or an immediate family member during the present calendar year (for purposes of this paragraph, the terms ''ownership or investment interest,'' ''physician,'' and ''immediate family member'' have the same meaning as set forth in 42 CFR 403.902); or

(B) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services).

(iv) *Manufacturer of a device or medical supply* means an entity that meets the definition of applicable manufacturer in 42 CFR 403.902 because it is engaged in the production, preparation, propagation, compounding, or conversion of a device or medical supply that meets the definition of covered drug, device, biological, or

medical supply in 42 CFR 403.902, but not including entities under common ownership with such entity.

(v) *Target patient population* means an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that:

(A) Are set out in writing in advance of the commencement of the value-based arrangement; and

(B) Further the value-based enterprise's value-based purpose(s).

(vi) *Value-based activity.* (A) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(*1*) The provision of an item or service;

(*2*) The taking of an action; or

(*3*) The refraining from taking an action; and

(B) Does not include the making of a referral.

(vii) *Value-based arrangement* means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are:

(A) The value-based enterprise and one or more of its VBE participants; or

(B) VBE participants in the same value-based enterprise.

(viii) *Value-based enterprise* or *VBE* means two or more VBE participants:

(A) Collaborating to achieve at least one value-based purpose;

(B) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(C) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and

(D) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

(ix) *Value-based enterprise participant* or *VBE participant* means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient acting in their capacity as a patient.

(x) *Value-based purpose* means:

(A) Coordinating and managing the care of a target patient population;

(B) Improving the quality of care for a target patient population;

(C) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or

(D) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

(ff) *Value-based arrangements with substantial downside financial risk.* As used in section 1128B of the Act, ''remuneration'' does not include the exchange of payments or anything of value between a VBE and a VBE participant pursuant to a value-based arrangement if all of the following standards in paragraphs (ff)(1) through (8) of this section are met:

(1) The remuneration is not exchanged by:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) A manufacturer of a device or medical supply;

(vi) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

(2) The VBE (directly or through a VBE participant, other than a payor, acting on the VBE's behalf) has assumed through a written contract or a value-based arrangement (or has entered into a written contract or a value-based arrangement to assume in the next 6 months) substantial downside financial risk from a payor for a period of at least 1 year.

(3) The VBE participant (unless the VBE participant is the payor from which the VBE is assuming risk) is at risk for a meaningful share of the VBE's substantial downside financial risk for providing or arranging for the provision of items and services for the target patient population.

(4) The remuneration provided by, or shared among, the VBE and VBE participant:

(i) Is directly connected to one or more of the VBE's value-based purposes, at least one of which must be a value-based purpose defined in § 1001.952(ee)(14)(x)(A), (B), or (C);

(ii) Unless exchanged pursuant to risk methodologies defined in paragraph (ff)(9)(i) or (ii) of this section, is used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE has assumed (or has entered into a written contract or value-based arrangement to assume in the next 6 months) substantial downside financial risk;

(iii) Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and

(iv) Is not exchanged or used for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

(5) The value-based arrangement is set forth in writing, is signed by the parties in advance of, or contemporaneous with, the commencement of the value-based arrangement and any material change to the value-based arrangement, and specifies all material terms including:

(i) Terms evidencing that the VBE is at substantial downside financial risk or will assume such risk in the next 6 months for the target patient population;

(ii) A description of the manner in which the VBE participant (unless the VBE participant is the payor from which the VBE is assuming risk) has a meaningful share of the VBE's substantial downside financial risk; and

(iii) The value-based activities, the target patient population, and the type of remuneration exchanged.

(6) The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

(7) The value-based arrangement does not:

(i) Limit the VBE participant's ability to make decisions in the best interests of its patients;

(ii) Direct or restrict referrals to a particular provider, practitioner, or supplier if:

(A) A patient expresses a preference for a different practitioner, provider, or supplier;

(B) The patient's payor determines the provider, practitioner, or supplier; or

(C) Such direction or restriction is contrary to applicable law under titles XVIII and XIX of the Act; or

(iii) Induce parties to reduce or limit medically necessary items or services furnished to any patient.

(8) For a period of at least 6 years, the VBE or VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this paragraph (ff).

(9) For purposes of this paragraph (ff), the following definitions apply:

(i) *Substantial downside financial risk* means:

(A) Financial risk equal to at least 30 percent of any loss, where losses and savings are calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a *bona fide* benchmark designed to approximate the expected total cost of such care;

(B) Financial risk equal to at least 20 percent of any loss, where:

(*1*) Losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor to a *bona fide* benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care; and

(*2*) The parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting; or

(C) The VBE receives from the payor a prospective, per-patient payment that is:

(*1*) Designed to produce material savings; and

(*2*) Paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services.

(ii) *Meaningful share* means the VBE participant:

(A) Assumes two-sided risk for at least 5 percent of the losses and savings, as applicable, realized by the VBE pursuant to its assumption of substantial downside financial risk; or

(B) Receives from the VBE a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services, and does not claim payment in any form from the payor for the predefined items and services.

(iii) *Manufacturer of a device or medical supply, target patient population, value-based activity, value-based arrangement, value-based enterprise, value-based purpose,* and *VBE participant* shall have the meaning set forth in paragraph (ee) of this section.

(gg) *Value-based arrangements with full financial risk.* As used in section 1128B of the Act, ''remuneration'' does not include the exchange of payments or anything of value between the VBE and a VBE participant pursuant to a value-based arrangement if all of the standards in paragraphs (gg)(1) through (9) of this section are met:

(1) The remuneration is not exchanged by:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) A manufacturer of a device or medical supply;

(vi) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

(2) The VBE (directly or through a VBE participant, other than a payor, acting on behalf of the VBE) has assumed through a written contract or a value-based arrangement (or has entered into a written contract or a value-based arrangement to assume in the next 1 year) full financial risk from a payor.

(3) The value-based arrangement is set forth in writing, is signed by the parties, and specifies all material terms, including the value-based activities and the term.

(4) The VBE participant (unless the VBE participant is a payor) does not claim payment in any form from the payor for items or services covered under the contract or value-based arrangement between the VBE and the payor described in paragraph (2).

(5) The remuneration provided by, or shared among, the VBE and VBE participant:

(i) Is directly connected to one or more of the VBE's value-based purposes;

(ii) Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and

(iii) Is not exchanged or used for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

(6) The value-based arrangement does not induce parties to reduce or limit medically necessary items or services furnished to any patient.

(7) The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

(8) The VBE provides or arranges for a quality assurance program for services furnished to the target patient population that:

(i) Protects against underutilization; and

(ii) Assesses the quality of care furnished to the target patient population.

(9) For a period of at least 6 years, the VBE or VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this paragraph (gg).

(10) For purposes of this paragraph (gg), the following definitions apply:

(i) *Full financial risk* means the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year.

(ii) *Prospective basis* means that the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to the provision of items and services to patients in the target patient population.

(iii) *Items and services* means health care items, devices, supplies, and services.

(iv) *Manufacturer of a device or medical supply, target patient population, value-based activity, value-based arrangement, value-based enterprise, value-based purpose,* and *VBE participant* shall have the meaning set forth in paragraph (ee) of this section.

(hh) *Arrangements for patient engagement and support to improve quality, health outcomes, and efficiency.* As used in section 1128B of the Act, ''remuneration'' does not include a patient engagement tool or support furnished by a VBE participant to a patient in the target patient population of a value-based arrangement to which the VBE participant is a party if all of the conditions in paragraphs (hh)(1) through (9) of this section are met:

(1) The VBE participant is not:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) A manufacturer of a device or medical supply, unless the patient engagement tool or support is digital health technology;

(vi) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services);

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supply; or

(viii) A manufacturer of a device or medical supply that was obligated under 42 CFR 403.906 to report one or more ownership or investment interests held by a physician or an immediate family member during the preceding calendar year, or that reasonably anticipates that it will be obligated to report one or more ownership or investment interests held by a physician or an immediate family member during the present calendar year, even if the patient engagement tool or support is digital health technology (for purposes of this paragraph, the terms ''ownership or investment interest,'' ''physician,'' and ''immediate family member'' have the same meaning as set forth in 42 CFR 403.902).

(2) The patient engagement tool or support is furnished directly to the patient (or the patient's caregiver, family member, or other individual acting on the patient's behalf) by a VBE participant that is a party to the value-based arrangement or its eligible agent.

(3) The patient engagement tool or support:

(i) Is an in-kind item, good, or service;

(ii) That has a direct connection to the coordination and management of care of the target patient population;

(iii) Does not include any cash or cash equivalent;

(iv) Does not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program;

(v) Is recommended by the patient's licensed health care professional; and

(vi) Advances one or more of the following goals:

(A) Adherence to a treatment regimen determined by the patient's licensed health care professional.

(B) Adherence to a drug regimen determined by the patient's licensed health care professional.

(C) Adherence to a followup care plan established by the patient's licensed health care professional.

(D) Prevention or management of a disease or condition as directed by the patient's licensed health care professional.

(E) Ensure patient safety.

(4) The patient engagement tool or support is not funded or contributed by:

(i) A VBE participant that is not a party to the applicable value-based arrangement; or

(ii) An entity listed in paragraph (hh)(1) of this section.

(5) The aggregate retail value of patient engagement tools and supports furnished to a patient by a VBE participant on an annual basis does not exceed $500. The monetary cap set forth in this paragraph (hh)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. OIG will publish guidance after September 30 of each year reflecting the increase in the CPI–U for the 12-month period ending September 30 and the new monetary cap applicable for the following calendar year.

(6) The VBE participant or any eligible agent does not exchange or use the patient engagement tools or supports to market other reimbursable items or services or for patient recruitment purposes.

(7) For a period of at least 6 years, the VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish that the patient engagement tool or support was distributed in a manner that meets the conditions of this paragraph (hh).

(8) The availability of a tool or support is not determined in a manner that takes into account the type of insurance coverage of the patient.

(9) For purposes of this paragraph (hh), the following definitions apply:

(i) *Eligible agent* means any person or entity that is not identified in paragraphs (hh)(1)(i) through (viii) of this section as ineligible to furnish protected tools and supports under this paragraph.

(ii) *Coordination and management of care, target patient population, value-based arrangement, VBE, VBE participant, manufacturer of a device or medical supply,* and *digital health technology* shall have the meaning set forth in paragraph (ee) of this section.

(ii) *CMS-sponsored model arrangements and CMS-sponsored model patient incentives.*

(1) As used in section 1128B of the Act, ''remuneration'' does not include an exchange of anything of value between or among CMS-sponsored model parties under a CMS-sponsored model arrangement for which CMS has determined that this safe harbor is available if all of the following conditions are met:

(i) The CMS-sponsored model parties reasonably determine that the CMS-sponsored model arrangement will advance one or more goals of the CMS-sponsored model;

(ii) The exchange of value does not induce CMS-sponsored model parties or other providers or suppliers to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient;

(iii) The CMS-sponsored model parties do not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of the CMS-sponsored model;

(iv) The CMS-sponsored model parties in advance of or contemporaneous with the commencement of the CMS-sponsored model arrangement set forth the terms of the CMS-sponsored model arrangement in a signed writing. The writing must specify at a minimum the activities to be undertaken by the CMS-sponsored model parties and the nature of the remuneration to be exchanged under the CMS-sponsored model arrangement;

(v) The parties to the CMS-sponsored model arrangement make available to the Secretary, upon request, all materials and records sufficient to establish whether the remuneration was exchanged in a manner that meets the conditions of this safe harbor; and

(vi) The CMS-sponsored model parties satisfy such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

(2) As used in section 1128B of the Act, ''remuneration'' does not include a CMS-sponsored model patient incentive for which CMS has determined that this safe harbor is available if all of the following conditions are met:

(i) The CMS-sponsored model participant reasonably determines that the CMS-sponsored model patient incentive will advance one or more goals of the CMS-sponsored model;

(ii) The CMS-sponsored model patient incentive has a direct connection to the patient's health care unless the participation documentation expressly specifies a different standard;

(iii) The CMS-sponsored model patient incentive is furnished by a CMS-sponsored model participant (or by an agent of the CMS-sponsored model participant under the CMS-sponsored model participant's direction and control), unless otherwise specified by the participation documentation;

(iv) The CMS-sponsored model participant makes available to the

Secretary, upon request, all materials and records sufficient to establish whether the CMS-sponsored model patient incentive was distributed in a manner that meets the conditions of this safe harbor; and

(v) The CMS-sponsored model patient incentive is furnished consistent with the CMS-sponsored model and satisfies such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

(3) For purposes of this paragraph (ii), the following definitions apply:

(i) *CMS-sponsored model* means:

(A) A model being tested under section 1115A(b) of the Act or a model expanded under section 1115A(c) of the Act; or

(B) The Medicare shared savings program under section 1899 of the Act.

(ii) *CMS-sponsored model arrangement* means a financial arrangement between or among CMS-sponsored model parties to engage in activities under the CMS-sponsored model that is consistent with, and is not a type of arrangement prohibited by, the participation documentation.

(iii) *CMS-sponsored model participant* means an individual or entity that is subject to and is operating under participation documentation with CMS to participate in a CMS-sponsored model.

(iv) *CMS-sponsored model party* means:

(A) A CMS-sponsored model participant; or

(B) Another individual or entity whom the participation documentation specifies may enter into a CMS-sponsored model arrangement.

(v) *CMS-sponsored model patient incentive* means remuneration not of a type prohibited by the participation documentation that is furnished to a patient under the terms of a CMS-sponsored model.

(vi) *Participation documentation* means the participation agreement, legal instrument setting forth the terms and conditions of a grant or cooperative agreement, regulations, or model-specific addendum to an existing contract with CMS that specifies the terms of a CMS-sponsored model.

(4) For purposes of remuneration that satisfies this paragraph (ii), the safe harbor protects:

(i) For a CMS-sponsored model governed by participation documentation other than the legal instrument setting forth the terms and conditions of a grant or a cooperative agreement, the exchange of remuneration between CMS-sponsored model parties that occurs on or after the first day on which services under the CMS-sponsored model begin and no later than 6 months after the final payment determination made by CMS under the model;

(ii) For a CMS-sponsored model governed by the legal instrument setting forth the terms and conditions of a grant or cooperative agreement, the exchange of remuneration between CMS-sponsored model parties that occurs on or after the first day of the period of performance (as defined at 45 CFR 75.2) or such other date specified in the participation documentation and no later than 6 months after closeout occurs pursuant to 45 CFR 75.381; and

(iii) For a CMS-sponsored model patient incentive, an incentive given on or after the first day on which patient care services may be furnished under the CMS-sponsored model as specified by CMS in the participation documentation and no later than the last day on which patient care services may be furnished under the CMS-sponsored model, unless a different timeframe is established in the participation documentation. A patient may retain any incentives furnished in compliance with paragraph (ii)(2) of this section.

(jj) *Cybersecurity technology and related services.* As used in section 1128B of the Act, ''remuneration'' does not include nonmonetary remuneration (consisting of cybersecurity technology and services) that is necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity if all of the conditions in paragraphs (jj)(1) through (4) of this section are met.

(1) The donor does not:

(i) Directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated; or

(ii) Condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals.

(2) Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(3) A general description of the technology and services being provided and the amount of the recipient's contribution, if any, are set forth in writing and signed by the parties.

(4) The donor does not shift the costs of the technology or services to any Federal health care program.

(5) For purposes of this paragraph (jj) the following definitions apply:

(i) *Cybersecurity* means the process of protecting information by preventing, detecting, and responding to cyberattacks.

(ii) *Technology* means any software or other types of information technology.

(kk) *ACO Beneficiary Incentive Program.* As used in section 1128B of the Act, ''remuneration'' does not include an incentive payment made by an ACO to an assigned beneficiary under a beneficiary incentive program established under section 1899(m) of the Act, as amended by Congress from time to time, if the incentive payment is made in accordance with the requirements found in such subsection.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

■ 3. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 262a, 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

■ 4. Section 1003.110 is amended—

■ a. In the definition of ''Remuneration'' by adding paragraph (10); and

■ b. By adding in alphabetical order a definition for ''Telehealth technologies.''

The additions read as follows:

§ 1003.110 Definitions.

* * * * *

Remuneration * * *

* * * * *

(10) The provision of telehealth technologies by a provider of services, physician, or a renal dialysis facility (as such terms are defined for purposes of title XVIII of the Act) to an individual with end-stage renal disease who is receiving home dialysis for which payment is being made under part B of such title, if:

(i) The telehealth technologies are furnished to the individual by the provider of services, physician, or the renal dialysis facility that is currently providing the in-home dialysis, telehealth services, or other end-stage renal disease care to the individual, or has been selected or contacted by the individual to schedule an appointment or provide services;

(ii) The telehealth technologies are not offered as part of any advertisement or solicitation; and

(iii) The telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end-stage renal disease.

* * * * *

Telehealth technologies, for purposes of paragraph (10) of the definition of the term ''remuneration'' as set forth in this section, means hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for diagnosis, intervention, or ongoing care management.

* * * * *

Christi A. Grimm,

Principal Deputy, Inspector General.

Alex M. Azar II,

Secretary.

[FR Doc. 2020–26072 Filed 11–20–20; 4:30 pm]

BILLING CODE 4152–01–P

FEDERAL REGISTER

Vol. 85 Wednesday,

No. 232 December 2, 2020

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 486

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 486

[CMS–3380–F]

RIN 0938–AU02

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs) to increase donation rates and organ transplantation rates by replacing the current outcome measures with new transparent, reliable, and objective outcome measures and increasing competition for open donation service areas (DSAs).

EFFECTIVE DATE: These regulations are effective on February 1, 2021, except for amendment number 3 (further amending § 486.302), which is effective July 31, 2022.

Implementation date: The regulations will be implemented on August 1, 2022.

FOR FURTHER INFORMATION CONTACT: Diane Corning, (410) 786–8486; Jesse Roach, (410) 786–1000; Kristin Shifflett, (410) 786–4133; CAPT James Cowher, (410) 786–1948; or Alpha-Banu Wilson, (410) 786–8687.

SUPPLEMENTARY INFORMATION:

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

I. Background
A. The Importance of Organ Procurement Organizations and the Need To Reform the Organ Procurement System
B. Statutory and Regulatory Provisions
C. HHS Initiatives Related to OPO Services and Executive Order (E.O.) 13879
II. Summary of the Proposed Provisions and Responses to Public Comments
A. General Comments
B. Proposed Changes to Definitions (§ 486.302) and Proposed Changes to Outcome Requirements (§ 486.318)
1. General Comments About the Outcome Measures
2. Donation Rate § 486.318(d)(1)
3. Donor Definition § 486.302 and the ''Zero Organ Donors''
4. Organ Transplantation Rate § 486.302 and § 486.318(d)(2)
5. Organ Definition § 486.302
6. Donor Potential (§ 486.302 and § 486.318(d)(4))
a. Death That Is Consistent With Organ Donation § 486.302
i. Death Certificate Data
ii. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM)
b. Age 75 and Younger
c. Inpatient Deaths
d. Waiver Hospitals
7. Risk-Adjustments § 486.302 and § 486.318(d)(2)
a. Chronic Diseases
b. Race
c. Gender and Age
d. Ventilator Status
8. OPO Performance on Outcome Measures § 486.318(e) and § 486.302
9. Non-Contiguous States, Commonwealths, Territories, or Possessions § 486.318(e)(7)
10. Assessment and Data for the Outcome Measures § 486.318(f)
11. Implementation Timeline
12. Definitions § 486.302
C. Re-Certification and Competition Processes (§ 486.316)
1. Re-Certification of OPOs § 486.316(a)
2. De-Certification and Competition § 486.316(b)
3. Criteria to Compete § 486.316(c)
4. Criteria for Selection § 486.316(d)
5. Extension of the Agreement Cycle for Extraordinary Circumstances § 486.316(f)
D. Reporting of Data § 486.328
E. Proposed Change to the Quality Assessment and Performance Improvement Requirement (§ 486.348)
1. Death Record Review in QAPI
F. Response to Solicitation of Comments
1. Out of Scope
III. Provisions of the Final Rule
A. Proposed Changes to Definitions (§ 486.302) and Proposed Changes to Outcome Requirements (§ 486.318).
B. Re-Certification and Competition Processes (§ 486.316)
C. Proposed Change to the Quality Assessment and Performance Improvement Requirement (§ 486.348)
D. Solicitation of Comments (Including Changes to Re-Certification Cycle)
IV. Collection of Information Requirements
A. ICRs Regarding Re-Certification and Competition Processes (§ 486.316)
B. ICRs Regarding Condition: Reporting of Data (§ 486.328)
C. ICRs Regarding Quality Assessment and Performance Improvement (§ 486.348)
V. Regulatory Impact Analysis
A. Statement of Need
B. Scope of Review
C. Effects on OPO Performance
D. Anticipated Costs and Benefits
1. Effects on Medical Costs
2. Effects on Patients
3. Implementation and Continuing Costs
E. Effects on Medicare, Medicaid, and Private Payers
F. Effects on Small Entities, Effects on Small Rural Hospitals, Unfunded Mandates, and Federalism
1. Regulatory Flexibility Act
2. Small Rural Hospitals
3. Unfunded Mandates Reform Act
4. Federalism
G. Alternatives Considered
1. Changes to the Denominator
a. CALC as the Denominator
b. All Deaths, Age <= 75 as the Denominator
c. Total Population, Age <75
2. Changing the Confidence Interval
3. Changing the Threshold Rates
H. Accounting Statement and Table
I. Reducing Regulation and Controlling Regulatory Costs
J. Conclusion
Regulations Text

I. Background

A. The Importance of Organ Procurement Organizations and the Need To Reform the Organ Procurement System

Organ procurement organizations (OPOs) are vital partners in the procurement, distribution, and transplantation of human organs in a safe and equitable manner for all potential transplant recipients. The role of OPOs is critical to ensuring that the maximum possible number of transplantable human organs is available to individuals with organ failure who are on a waiting list for an organ transplant. There are currently 58 OPOs that are responsible for identifying eligible donors and recovering organs from deceased donors in the United States (U.S.), with no current statutory authority to add new OPOs. Therefore, the Centers for Medicare & Medicaid Services (CMS) views OPO performance as a critical element of the organ transplantation system in the United States (U.S.)

As of November 2020, a total of 108,725 people were on the waiting lists for a lifesaving organ transplant.[1] Many people face tremendous quality of life burdens or death while on the waiting list. An OPO that is efficient in procuring organs and delivering them to recipients will help more people on the waiting list receive lifesaving organ transplants, which could ultimately save more lives.

Based on public feedback and our own internal analysis of organ donation and transplantation rates, it is the agency's belief that the current OPO outcome measures are not sufficiently objective and transparent to ensure appropriate accountability in assessing OPO performance, nor do they properly incentivize the adoption of best practices and optimization of donation and organ placement rates.

[1] Organ Procurement and Transplantation Network (OPTN) Data. *https://optn.transplant.hrsa.gov/data/.*

Given OPOs' important role in the organ donation system in the U.S., some stakeholders have stated that underperformers have faced few consequences for poor performance, by noting ''Performance varies across the OPO network, with many persistent underperformers failing to improve over the last decade.'' [2] They further note that there are serious negative impacts to both organ transplantation and donation when OPOs are underperforming, in that ''[w]hen OPOs are inefficient or ineffective, donor hospitals are reluctant to refer potential donors, and transplant programs have fewer organ offers for patients on the waiting list. The end result is a bottleneck within the system that leads to avoidable deaths and increased national health care spending.'' [3]

Some stakeholders, including members of the OPO industry, have stated that the current OPO outcome measures should be reformed to incentivize improvements in OPO performance. Some of these stakeholders note that ''[e]xisting regulations need dramatic improvement to remove perverse incentives to organ procurement (for example, OPOs are evaluated on the number of organs procured per donor, which leads to older single-organ donors being overlooked) and increase continuous performance accountability.'' [2] Reforming the current outcome measures can be achieved, they indicated, through metrics that improve accountability and ''by replacing current ineffective metrics for OPO performance with a simplified transparent metric that enables independent performance measurement.'' [2]

B. Statutory and Regulatory Provisions

To be an OPO, an entity must meet the applicable requirements of both the Social Security Act (the Act) and the Public Health Service Act (the PHS Act). Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order for organ procurement costs to be paid under the Medicare program or the Medicaid program. Section 1138(b)(1)(A) of the Act specifies that payment may be made for organ procurement costs only if the agency is a qualified OPO operating under a grant made under section 371(a) of the PHS Act or has been certified or re-certified by the Secretary of the Department of Health and Human Services (the Secretary) as meeting the standards to be a qualified OPO within a certain time period. Section 1138(b)(1)(C) of the Act provides that payment may be made for organ procurement costs ''only if'' the OPO meets the performance-related standards prescribed by the Secretary. Section 1138(b)(1)(F) of the Act requires that to receive payment under the Medicare program or the Medicaid program for organ procurement costs, the entity must be designated by the Secretary. The requirements for such designation are set forth in 42 CFR 486.304 and include being certified as a qualified OPO by CMS.

Pursuant to section 371(b)(1)(D)(ii)(II) of the PHS Act, the Secretary is required to establish outcome and process performance measures for OPOs to meet based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of the qualified OPO. Section 1138(b)(1)(D) of the Act requires an OPO to be a member of, and abide by the rules and requirements of, the Organ Procurement and Transplantation Network (OPTN). OPOs must also comply with the regulations governing the operation of the OPTN (42 CFR part 121). The Department of Health and Human Services (HHS) has explained that only those policies approved by the Secretary will be considered ''rules and requirements'' of the OPTN for purposes of section 1138 of the Act. The OPTN is a membership organization that links all professionals in the U.S. organ donation and transplantation system. Currently, the United Network for Organ Sharing (UNOS) serves as the contractor for the operation of the OPTN under contract with HHS. OPOs are required under the OPTN final rule (42 CFR 121.11(b)(2)) and 42 CFR 486.328 of the OPO CfCs to report information specified by the Secretary to the OPTN, including the data used to calculate the outcome measures for OPOs.

In addition, OPOs are required to comply with title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d (title VI), section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 and section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116 (section 1557). Title VI and section 1557, protect individuals on the basis of race, color and national origin. Under these laws, OPOs are required to take reasonable steps to ensure meaningful access to their programs by individuals with limited English proficiency. Reasonable steps may include providing language assistance services at no cost, such as providing interpreters or translated material. Also, section 504 and section 1557 protect qualified individuals with a disability, including prospective organ recipients with a disability and prospective organ donors with a disability, from discrimination in the administration of organ transplant programs. Under these laws, OPOs must ensure that qualified individuals with a disability are afforded opportunities to participate in or benefit from the organ transplant programs that are equal to opportunities afforded others. Decisions to approve or deny organ transplants must be made based on objective facts related to the individual in question. ''Individuals with disabilities are also entitled to reasonable accommodations needed to participate in and benefit from a program, and auxiliary aids and services needed for effective communication. These rights extend in some circumstances to family members of a prospective organ donor or recipient. For example, health care providers and organ donation programs are required to provide auxiliary aids and services (including sign language interpreters) when necessary for effective communication between a relative involved in a prospective donor or recipient's care and a health care provider or donation program.'' Additionally, if eligibility criteria for being a transplant recipient require an individual to be able to comply with post-transplant regimens, it would be a reasonable accommodation to allow an individual with a developmental or intellectual, or other disability to meet that requirement with the assistance of a relative, attendant, or other individual.

We established CfCs for OPOs at 42 CFR part 486, subpart G, and OPOs must meet these requirements in order to be able to receive payments from the Medicare and Medicaid programs. These regulations set forth the certification and re-certification processes, outcome requirements, and process performance measures for OPOs and became effective on July 31, 2006 (71 FR 30982), which we refer to as the ''2006 OPO final rule''. The current outcome measures, found under § 486.318, are used to assess OPO performance for re-certification and competition purposes (see § 486.316(a) and (d)).

Section 486.322 requires that an OPO must have a written agreement with 95 percent of the Medicare- and Medicaid-participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room, and have not been granted a waiver by CMS to work with another OPO. Meanwhile, 42 CFR 482.45

[2] The Bridgespan Group. Reforming Organ Donation in America. *https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf.*

[3] ORGANIZE. Organ Donation Reform Report, 2019.

requires a hospital have written protocols that incorporate an agreement with an OPO under which it must notify, in a timely manner, the OPO or a third party designated by the OPO, of individuals whose death is imminent or who have died in the hospital. Potential organ donors may encounter Medicare- and Medicaid-certified providers prior to an emergency department visit or hospital admission to a critical care unit. Therefore, we expect that each OPO's responsibilities and work begins long before a hospital notifies the OPO of an impending death—through, but not limited to, extensive training and education of all Medicare and Medicaid-certified providers along the continuum of care and by fostering a collaborative relationship among them.

C. HHS Initiatives Related to OPO Services and Executive Order (E.O.) 13879

In 2000, the Secretary's Advisory Committee on Organ Transplantation (ACOT) was established under the general authority of section 222 of the PHS Act, as amended. See 42 CFR 121.12. ACOT is charged to: (1) Advise the Secretary, acting through the Administrator, Health Resources and Services Administration (HRSA) on all aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines; (2) advise the Secretary on federal efforts to maximize the number of deceased donor organs made available for transplantation and to support the safety of living organ donation; (3) at the request of the Secretary, review significant proposed OPTN policies submitted for the Secretary's approval to recommend whether they should be made enforceable; and (4) provide expert input to the Secretary on the latest advances in the science of transplantation, the OPTN's system of collecting, disseminating and ensuring the validity, accuracy, timeliness and usefulness of data, and additional medical, public health, patient safety, ethical, legal, financial coverage, social science, and socioeconomic issues that are relevant to transplantation.[4]

A 2012 recommendation by ACOT stated: ''The ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and OPOs and that the current system lacks responsiveness to advances in TCs and OPO performance metrics. The ACOT recommends that the Secretary direct CMS and HRSA to confer with the OPTN, Scientific Registry of Transplant Recipients (SRTR), the OPO community, and TCs representatives to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on TCs and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs . . . .''[5]

On July 10, 2019, President Trump issued Executive Order (E.O.) 13879 titled ''Advancing American Kidney Health.'' The E.O. 13879 states that it is the policy of the U.S. to ''prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care; increase patient choice through affordable alternative treatments for end-stage renal disease (ESRD) by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.''

Further, the E.O. 13879 aims to increase the utilization of available organs by ordering that, within 90 days of the date of the order, the Secretary propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising OPO rules and evaluation metrics to establish more transparent, reliable, and enforceable objective outcome measures for evaluating an OPO's performance. In conjunction with the E.O. 13879, HHS set a goal to deliver more organs for transplantation and aims to double the number of kidneys available for transplant by 2030.[6]

In accordance with the E.O. 13879, we published a proposed rule in the **Federal Register** on December 23, 2019 entitled, ''Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations'' (84 FR 70628 through 70710), (referred to as the ''December 2019 OPO proposed rule''), which proposed to revise the current OPO outcome and process measures to be more transparent, reliable, and provide enforceable objective outcome measures of OPO performance. The December 2019 OPO proposed rule would improve upon the current measures by using objective and reliable data, incentivize OPOs to ensure all viable organs are transplanted, hold OPOs to greater oversight while driving higher performance, and as a result, save more lives.

II. Summary of the Proposed Provisions and Responses to Public Comments

In response to the December 2019 OPO proposed rule (84 FR 70628 through 70710), we received approximately 834 total comments. Commenters included individual OPOs, transplant hospitals, national associations and coalitions, academic researchers, advocacy organizations, health care professionals and corporations, donor families, and numerous individuals from of the general public. Most commenters supported the proposed rule's goals to improve organ donation and transplantation in the U.S. and to update the current OPO outcome measures.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and an explanation for changes in the policies that we are finalizing. We note that this final rule is written in order by topic, discussing our primary reason for revising the regulations by revising the outcome measures first, and then discussing some necessary changes and cross-cutting requirements.

A. General Comments

The majority of the comments received on the December 2019 OPO proposed rule were received from the general public and organ donor families.

Comment: The majority of the commenters asked for OPOs to be held accountable for poor performance and for additional oversight of OPOs. Some of the commenters expressed concern that the OPOs are operating as monopolies that are engaged in fraud, waste, and abuse. Many commenters asked CMS to increase the accessibility of organs for transplant and ensure that donated organs reach the many individuals on the organ transplant waitlist.

The comments received from donor families expressed support for the OPO in their service area and expressed concern that the proposed changes

[4] *https://www.organdonor.gov/about-dot/acot/charter.html.*

[5] Available at: *https://www.organdonor.gov/about-dot/acot/acotrecs55.html.*

[6] *https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.*

would lead to the decertification of their assigned OPO.

Response: We appreciate the commenters' feedback. The tremendous amount of comments that we received asking for OPOs to be held accountable strongly supports our commitment to reform the organ donation and transplantation system in the U.S. We believe that the changes we are making in assessing OPO performance will ensure positive outcomes and increases in the organ supply. There are other initiatives that HHS and CMS are currently undertaking that will also lead to improvements in organ donation and transplantation, such as the ESRD Treatment Choice (ETC) Kidney Transplant Learning Collaborative.

We also appreciate the time taken by numerous donor families to develop and submit thorough and thoughtful comments on the proposed rule. We understand that the decision to donate a family member's organs is difficult, and we praise these families for their generosity. We acknowledge that the decision to donate their loved one's organs likely saved or improved the recipient's life. The changes that we discuss in this final rule are intended to ensure that donated organs are not wasted and reach those waiting for a lifesaving organ transplant. It is our goal to ensure that OPOs are held to a high level of performance expectations and that all OPOs are pushed to perform better. We acknowledge that through changes to the procurement and transplantation process (such as enacting best practices) we can effect visible changes that can lead to an increase in the number of organs available for transplant and decreases in organ discards. We acknowledge commenters' concerns regarding decertification of OPOs and note that that is a likely potential outcome due to these new measures. However, CMS is committed to ensuring patient access to high quality health care, including access to high performing OPOs. Additionally, we believe the measures will incentivize OPOs to improve result in upward performance across most, if not all, OPOs.

Comment: Several commenters criticized our reference to the Bridgespan study [2] and objected to our characterization of the failures of OPOs. These commenters also expressed concern about negative stories in the media suggesting that OPOs are poorly performing and do not care about the families they serve. The commenters stated that when media stories share inaccurate or outright false information about the OPO community, these stories have the strong potential to hurt public perceptions about donation.

Response: We understand that there have been several news articles about the poor performance of some OPOs and some of these articles raise reasons about why the organ donation system needs to be reformed. Our independent assessment of OPO performance on outcome measures is the basis for our belief that more oversight is needed. As of November 2020, a total of 108,591 people were on the waiting lists for lifesaving organ transplants. An OPO that is efficient in procuring organs and delivering them to recipients will help more people on the waiting list receive an organ transplant, which could ultimately save more lives. The current OPO outcome measures are not sufficiently objective and transparent to ensure public trust in assessing OPO performance, nor do they properly incentivize the adoption of best practices and optimization of donation and organ replacement rates. Given these concerns, as well as those regarding the data quality of self-reported measures, we are finalizing new outcome measures at § 486.318 to hold OPOs accountable as a crucial step in reforming the organ donation system.

B. Proposed Changes to Definitions (§ 486.302) and Proposed Changes to Outcome Requirements (§ 486.318)

In the December 2019 OPO proposed rule, we proposed to revise the outcome measures for re-certification and the corresponding changes in definitions at §§ 486.302 and 486.318 to replace the current outcome measures and definitions. We proposed at § 486.302 the definition of ''donation rate'' as the number of donors as a percentage of the donor potential. We also proposed to add ''donor potential,'' as the number of inpatient deaths within the donation service area (DSA) among patients 75 years of age and younger with any cause of death that would not be an absolute contraindication to organ donation. We also proposed to define the term ''organ transplantation rate,'' which is discussed in more detail in section II.B.4 of this final rule and changes related to our use of ''death that is not an absolute contraindication to organ donation'' at § 486.302 of this final rule. We refer readers to section II.B of this final rule for the other definitions we proposed at § 486.302. We proposed to revise the outcome measures for re-certification at § 486.318 to replace the current existing outcome measures with the proposed two new outcome measures that would be used to assess an OPO's performance: ''donation rate'' and ''organ transplantation rate'' effective for calendar year (CY) 2022. We have organized the comments by subject matter.

The comments and our responses are below.

1. General Comments About the Outcome Measures

Comment: Several commenters, supported our proposed new outcome measures while other commenters questioned the need for revising them. Some commenters in support of the proposed new outcome measures recognized that these measures are derived from objective data and would not present an increased burden on OPOs. One commenter was concerned that the proposed new outcome measures would result in the OPOs putting more pressure on families and next-of-kin to authorize organ donations. Other commenters expressed concern that increased pressure from the proposed outcome measures and the threat of de-certification (discussed in section II.C of this final rule) would damage the relationships between the OPOs so that they will no longer cooperate with one another.

Response: We appreciate the comments received on the proposed outcome measures. Under our current regulations, the outcome measures at § 486.318 are used to assess OPO performance for re-certification and to determine the selection of an OPO to take over a DSA as part of the competition for an open DSA. We think the increased transparency and objectivity of the proposed outcome measures will drive improvements in organ donation and transplantation while reducing reporting burdens for OPOs. As discussed in section II.B.1 of this final rule, there are aspects of our current outcome measures that we no longer find adequate; therefore, we believe that revising the current outcome measures would be consistent with the goal of E.O. 13879, which directs CMS to establish more transparent, reliable, and enforceable objective measures for evaluating an OPO's performance. In addition, we believe revising the current outcome measures is a critical step towards achieving the Secretary's goal of doubling kidneys available for transplantation by 2030.

Our proposed outcome measures are based on verifiable and objective data and are designed to increase organ transplantations by comparing an OPO's performance to the top performing OPOs. The top performing OPOs have demonstrated success in their role and responsibilities using practices that do not place inappropriate pressures on

families to consent to an organ donation. We note that studies have shown that giving families sufficient time to make their informed decisions and not putting too much pressure on families results in successful consent.[7] We also note that by objectively identifying top performing OPOs, poorer performing OPOs can appropriately change and adopt their effective practices that improve their performance in donation and make more organs available for transplantation.

It is clear that our historical approach to measuring OPO performance has resulted in a wide range of performances. This variability is unacceptable to patients and CMS. Thus, CMS intends to hold these entities to revised and higher standards. These revised metrics are necessary in light that over the past 14 years, the sharing of best practices, if it has occurred, has not resulted in consistent improvements throughout the industry. CMS is committed to increasing the availability of organs for transplantation across all DSAs, and continues to believe that this higher standard is necessary to achieve this goal.

Comment: We received multiple comments raising concerns that removing organs for research, other than the pancreata, as part of the outcome measures would hurt research by discouraging OPOs from using organs that are not transplanted for research. A commenter recommended CMS to include organs that are used in organ transplantation research in the outcome measures because the process for obtaining consent and managing these donors is the same as with organ transplantation. Other commenters suggested that we include organs for research as a ''third performance metric'' or incorporate it in some other way into our conditions. One commenter discussed our history of inclusion of organs for research and stated that OPOs would not pursue marginal organs because they would no longer get credit if the organ was not transplanted, whereas the old outcome measures allowed them to be counted to the organs for research measure.

Response: We appreciate the comments raising concerns about the removal of other organs used for research as part of the outcome measures.

The transplant and research communities commonly described the transplantation of organs into humans using research protocols (for example, deceased donor intervention research) as both transplants and research. Generally, such research involves the transplantation of organs into transplant candidates that is generally considered clinical care while simultaneously qualifying as human subject research. For the purpose of establishing the performance measures, we contend that organs used for research is meant to apply only to organs procured and used only for research purposes. Organs transplanted into human subjects are counted as part of clinical care. Although organs procured for research may sometimes involves the same procedures and practices of donor management as organs for transplantation, we cannot easily verify the procurement of organs for research unless they are transplanted into a patient on the OPTN waiting list. Furthermore, our concern is that having an outcome measure for organs procured for research may inadvertently incentivize OPOs to direct some organs for research rather than for transplantation. Except for pancreata when procured for research, as noted in the December 2019 OPO proposed rule, we are not adopting the commenters' suggestion to include organs donated for research in the outcomes measures.

Pancreata procured for islet cell research are included in the outcome measures of this final rule. We carefully considered other options to address pancreata procured for research, such as creating a process measure for these organs, creating a unique outcome measure, and counting these organs in the outcome measures of this final rule as less than the full value of a transplanted organ. However, these alternative policy approaches did not meet the PHS Act, which states that ''Pancreata procured by an organ procurement organization (OPO) and used for islet cell transplantation or research shall be counted for purposes of certification or recertification . . . .'' To meet this statutory requirement, we have chosen to include pancreata for research in the outcome measures in the same way that organs procured for transplantation are included. We think that the impact of pancreata for research on the overall rankings of OPOs will continue to be minimal. From 2014 to 2018 (the most recent year of complete data), the number of pancreata procured for research has been 727, 716, 575, and 579. There is a clear downward trend, and we expect that this trend will continue or level off. Our internal analysis demonstrated little effect on the rankings of OPOs from including or excluding pancreata for research when calculating performance on both the donor and transplant measures of this final rule. A particular OPO may move up or down 1–3 ranking spots based on the inclusion of this data, but no OPOs moved in such a way that it impacted whether they would be eligible for automatic recertification or would be automatically decertified. We will continue to monitor the trends of pancreata procured for research and will use the survey process to conduct further investigation into any anomalies that such monitoring reveal.

Comment: We solicited comments as to whether we should consider assessing OPO performance based on organ-specific transplant rates and received a comment that broadly supported this approach, but we did not receive details about how we would measure success for the organ-specific transplant rates or how it could be implemented.

Response: We are not including organ-specific transplantation rates in our outcome measures because we do not believe that organ-specific transplantation rates would provide an additive assessment of OPO performance and achieve our goals of increasing organs available for transplantation.

2. Donation Rate §§ 486.302 and 486.318(d)(1)

In the December 2019 OPO proposed rule, we proposed to include at § 486.302 the definition the ''donation rate'' as the number of donors as a percentage of the donor potential. In current regulations at § 486.318(d)(1), we define the donation rate as being the eligible donors as a percentage of the eligible deaths.

In addition, we proposed that § 486.318(d)(1) specifies that the donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

Comment: The majority of the comments received supported the use of the donation rate to measure OPO performance.

Response: We appreciate the comments received. We consider the donation rate to be an important outcome measure because it assesses the ability of the OPO to obtain consent from the donor family, successfully manage the donor, procure and place at least one organ for transplantation (or pancreas for research), and ensure the safe transport of that organ for transplantation. However, despite all these aspects of the OPO's role that the donation rate measures, for patients waiting for a life-saving organ

[7] Siminoff, LA, Agyemang, AA, et al., ''Consent to organ donation: a review,'' Prog Transplant. 2013 Mar; 23(1): 99–104.

transplant, the primary measure of interest is the organ transplantation rate. Therefore, the donation rate can be seen as augmenting the organ transplantation rate. By including the donation rate, we incentivize OPOs to pursue all donors, especially the single organ donors. An OPO is more likely to meet the donation rate measure if they also procure organs from donors after cardiac death (DCD) or marginal donors where relatively fewer organs may be transplantable.

Comment: One commenter suggested CMS measure the OPOs ability to obtain consent in calculating the donation rate. The commenter did not suggest how the consent would be used as an outcome measure.

Response: Although obtaining consent is one part of the donation process, we are not adopting the commenter's suggestion to use obtaining consent as an outcome measure. We recognize the critical role of obtaining consent as the first part of donation, and without it, the rest of the donation process cannot occur. Our regulation at § 486.342 requires OPOs to have a written protocol to ensure that, in the absence of a donor document, the individual(s) responsible for making the donation decision are informed of their options to donate organs or tissues (when the OPO is making a request for tissues) or to decline to donate. As with our other CfCs, we survey to ensure compliance with this requirement, and those surveys typically occur every 4 years. However, we cannot verify success in obtaining consent relative to the donor referrals through independent, objective data on an annual basis and instead, rely on surveys. It would be unduly burdensome to OPOs to be routinely surveyed every year for us to identify and verify this information for purposes of the frequent assessment periods in which these outcome measures are calculated to trigger revisions to the Quality Assessment and Performance Improvement (QAPI) plan under the requirements at § 486.348 (also discussed in section II.E of this final rule).

Final Rule Action: We are finalizing as proposed the definition of donation rate at § 486.302, which is defined as the number of donors as a percentage of the donor potential. Furthermore, we are finalizing at § 486.318(d) that an OPO is evaluated by measuring the donation rate in their DSA and at § 486.318(d)(1) the donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

3. Donor Definition (§ 486.302) and the ''Zero Organ Donors''

In the December 2019 OPO Proposed rule, we proposed to revise the definition of ''donor'' at § 486.302 to mean a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured for research or islet cell transplantation. In general, the proposed definition of donor would change the current regulatory definition, requiring that at least one organ be transplanted, rather than being recovered for the purpose of transplantation, in order for the donor to be included in the donation rate. We also included donors who had pancreata procured for islet cell transplantation and research in the definition of donor to respond to the requirements of section 371(c) of the PHS Act.

Comment: Several commenters stated that our proposed new definition of ''donor'' excluded ''zero organ donors.'' Some commenters had different definitions of ''zero organ donors'' including: (1) Donors who are taken to the operating room but cannot be a donor for one or more reasons; and (2) are donors in which the transplantable organs are turned down by transplant programs. These commenters claim that excluding ''zero organ donors'' in the donation rate would discourage OPOs from pursuing extended criteria or marginal and complex donors, which would be inconsistent with our goal of trying to increase donations, particularly of single organ donors.

Response: We acknowledge that the general effect of our proposed definition of donor at § 486.302 would be that, a patient must donate at least one organ that is actually transplanted to qualify as a ''donor.'' We note that the definition also includes a patient who donates a pancreas for research. Although ''zero organ donors'' would not fall under this definition, we are not persuaded by comments that OPOs will not pursue the extended criteria or marginal, complex donors if we do not include ''zero organ donors'' in the outcome measures. Not only did we receive comments from some OPOs stating that they are committed to ''pursuing every organ every time even if no organs are transplanted,'' but an OPO that does not pursue these donors will be at risk of being identified as a poorer performer compared to other OPOs and could possibly face the prospect of being de-certified.

Evidence demonstrates that the top performing OPOs are pursuing extended criteria and single-organ donors, and those OPOs are also successfully placing the organs at programs that transplant them. Some OPOs are relatively successful in recovering organs from more marginal candidates, saving those donors from being ''zero organ donors.'' We accessed the OPTN database on August 12, 2020 and found that from 2018 and 2019, the OPO in Nevada had procured 80 kidneys that were categorized as having the highest Kidney Donor Profile Index (KDPI) scores of 86 through 100. These types of kidneys are primarily from extended criteria or marginal donors that are more likely to end up as ''zero organ donors.'' Meanwhile, the local kidney transplant programs in their DSA transplanted zero kidneys with the highest KDPI scores, meaning that these organs were transplanted by programs outside of their DSA; this example suggests that the local demand was not driving the Nevada OPO's performance. In order for other OPOs to follow this example, they must also pursue the extended criteria and marginal donors, even if the local transplant program does not accept them. Using the comparative performance methodology and holding all OPOs to the performance of these top performing OPOs, we intend to incentivize all OPOs to pursue extended criteria and marginal donors, even if they may become zero organ donors.

Comment: Some commenters recognized that ''zero organ donor'' counts are self-reported data and are difficult to verify, but suggested that CMS review the charts or use triggers to lead to a chart audit as a means of verifying these donors.

Response: In changing the definition of donor, we are adhering to the principles described in the December 2019 OPO proposed rule that the outcome measures be more transparent, reliable, and objective measures of OPO performance. Part of ensuring reliability is moving away from self-reported data as much as is feasible and using data that can be easily verified. It would require an extraordinary effort for CMS to verify the zero organ donors as frequently as needed to calculate the annual assessments of OPO outcome measures that will be used to trigger revisions of the QAPI program that can spur OPOs to improve their performance, and to rank OPOs for certification purposes.

Comment: We received several comments stating that because it is ultimately the transplant programs that decide whether an organ is transplanted (not the OPO) that redefining ''donor'' to require that the organ be transplanted would not be appropriate.

Response: Transplant programs decide whether an organ will be transplanted; however, it is the OPO's responsibility to ensure that placement and transport of organs happen in a fast and effective manner. If the OPO engages in best practices for placement, packaging, and transportation of organs, such as using RFID tags to track organs in transit and assure that they are not forgotten or diverted, there should not be significant differences in the frequency of zero organ donors among OPOs because the occurrence of unexpected anatomical issues which contraindicate donation that arise after consent is secured are random and not statistically significant in one DSA compared to another.

Comment: Several commenters stated that OPOs are obligated to the allocation system and that sometimes they run out of time trying to place certain organs. Therefore, the commenters stated that the OPOs should not be punished if they cannot place a transplantable organ.

Response: We respectfully disagree with the commenters' assertion. The OPTN final rule has a section on wastage that explicitly allows transplant programs to transplant an organ into any medically suitable candidate to do otherwise would result in the organ not being used for transplantation (42 CFR 121.7(f)). Therefore, we do not believe the constraints of the allocation system justify not successfully placing a transplantable organ. We believe that this final rule will allow OPOs the opportunity to improve the placement of organs, and drive the transplant community to adopt the technologies necessary to optimize placement.

Comment: We received a comment that there are some events, such as loss of an organ during transport, which OPOs cannot control.

Response: By requiring that the organ be actually transplanted (with the exception of pancreata procured for research) in order to be counted in the donation rate, we are supporting those OPOs that work to successfully complete the final step of the donation process. Unfortunately, we are aware of incidences where organs are lost or damaged during transport.[8] It is the responsibility of the OPO to arrange the appropriate transport to the transplant program. (See § 486.346 of this final rule.) Therefore, it is important that any measure of OPO performance not stop at the procurement of a transplantable organ, but also holds OPOs accountable for the subsequent steps for successful placement and transport of organs.

Comment: One commenter suggested that donor families would be disappointed if they consented to the donation, but we did not allow the zero organ donor to be called a donor.

Response: We appreciate every potential donor and are not discouraging OPOs from referring to ''zero organ donors'' as ''organ donors'' even if no organs are transplanted when speaking with families. The use of the term ''organ donors'' has different meanings in different settings. Many families consider their loved ones to be organ donors if they are eye and tissue donors or if the organs are donated for research. Therefore, we do not think our definition, used solely for assessing OPO performance for regulatory purposes, should affect the donor families' perception of the value of their loved one's donation or the terms used by OPOs or other organizations when liaising with families of potential donors.

Comment: One commenter stated that it was important to encourage OPOs to pursue all donors and suggested that we include these ''zero organ donors'' in the performance measures even if they are not included in the outcome measures.

Response: We will continue to work with OPOs on a more refined reporting process to capture information about zero organ donors and the reason for the organs not being retrieved or transplanted. We intend to continue the dialog with OPOs about the necessary data to collect and how to do so in a verifiable, burden neutral manner, and our CfCs may be revised in the future based on such modifications and further analysis of the data.

Comment: One commenter supported our proposed definition of donor because they agreed that OPOs could ''game the system'' if we included ''zero organ donors.''

Response: We appreciate the comment and, as explained above, we are not including ''zero organ donors'' in the definition of ''donor.'' As we stated in the December 2019 OPO proposed rule, we have concerns with self-reported data. Our internal analysis of the OPTN data found a variation in the frequency of ''zero organ donors'' as defined as a donor in which an organ was procured for transplantation, but no organ was transplanted. We did not see an association between the OPO's performance and the percentage of these donors, however, we retain the concerns expressed in the December 2019 OPO proposed rule. The OPTN data show that in 2018, there were 1,255 organs procured from these zero organ donors, but never transplanted. In that same year 31,203 organs were transplanted. Among the top performing OPOs, zero organ donors represented 2.73 percent to 11.86 percent of donors (the range among all OPOs was 0 percent to 17.02 percent) with counts ranging from 3 to 59 zero organ donors.

We do not understand the significance of this variation, but will continue to examine the data about ''zero organ donors'' and assess whether we can appropriately capture and verify the data for future inclusion in our outcome measures.

Comment: We received a comment raising concerns that the change in the definition of donor could affect reimbursement from Medicare since the previous definition allowed OPOs to be reimbursed for the efforts to procure transplantable organs.

Response: Our revised definition of donor does not impact Medicare reimbursement for organ procurement costs. We did not propose to change our rules for reimbursing OPOs for organ procurement costs. Our payment policies for organ procurement costs do not rely on our definition of donor under § 486.302.

Final Rule Action: We are finalizing as proposed in the December 2019 OPO proposed rule, the definition for donor at § 486.302 to mean a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured and is used for research or islet cell transplantation.

4. Organ Transplantation Rate (§ 486.302 and § 486.318(d))

For our second measure, we proposed to assess the OPO's organ transplantation rate, which is defined as the number of organs transplanted from donors in the DSA as a percentage of the donor potential.

Comment: We received a number of comments supporting our organ transplantation measure because it was a volumetric measure (that is, reflects the volume of organs transplanted). We had one OPO commenter provide an example of how they increased the procurement of lungs for transplantation, but the SRTR method for measuring observed to expected performance in organ transplantation did not capture their improved performance.

Response: We appreciate the comments in support of the volumetric organ transplantation measure. As

[8] Kaiser Health News, ''How Lifesaving Organs for Transplant Go Missing in Transit,'' February 10, 2020 *https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/.*

stated earlier, the organ transplantation rate is an important measure as it directly measures the benefit for patients from OPO performance.

Comment: Several commenters opposed the organ transplantation rate because it was too similar to, and not independent of, the donation rate since it shared the same denominator as the donation rate.

Response: In both of our outcome measures, the denominator represents a reasonable effort to estimate of the donor potential and other related factors for the DSA, as required by the OPO Certification Act of 2000.[9] The numerators measure OPO performance (through the number of donors and organs transplanted) and are somewhat correlated because if there are more donors, there are likely to be more organs transplanted. It is CMS' expectation that high-performing OPOs will likely perform well on both measures and low-performing OPOs will perform poorly on both measures. However, these numerators are not the same and each donor has a range of potential organs that could be transplanted. For example, OPOs that focus primarily on DCD and marginal donors may need to seek more donations in order to have sufficient organs transplanted to mathematically meet the organ transplantation rates. On the other hand, OPOs that are very effective at placing all possible organs from younger, healthier donors may achieve the targeted organ transplantation rate, but not the donation rate, if they choose not to pursue the marginal, complex and DCD donors with only one or two transplantable organs.

Comment: We received a number of comments from the OPO community recommending that we use the SRTR's Donor Yield model, which calculates an observed:expected (O:E) ratio for placing organs for transplantation (also called the SRTR O:E model). These commenters preferred the O:E measures because it includes 34 to 50 risk-adjustments, changes over time, and measures a different part of an OPO's performance from the donation rate (part that involves placement and transport an organ).

Response: While the SRTR's O:E ratio may have value for understanding potential areas for improvement and may be used by the OPTN and OPOs for internal performance assessment, it is derived from the donation rate and is not capable of assessing the number of organ transplants. The SRTR O:E model ''uses a series of complex statistical models'' and relies on coefficients from a multinominal regression model.[10] The validity of the model is dependent upon frequent updates to the regression analyses to determine which predictors are in the model (hence range of 34 to 50 risk-adjustments). Because of the complexity of the model and the need for frequent updating, it is not feasible for us to continually update the methodology through notice and comment rulemaking, which is necessary in order to enforce the current version of the model. Use of the SRTR O:E model in regulation has not been practicable. The mathematical complexity of the risk-adjustments creates an opacity that is inconsistent with our goal of increasing transparency in our outcome measures.

Comment: We received comments suggesting we add the SRTR's donor yield model, which measures observed to expected performance in O:E measure with the organ transplantation rate or increase the level of performance on the O:E measure.

Response: We appreciate the commenters recognizing that the O:E measure is based on the average performance of an OPO and suggesting that we retain the measure but increase the level of performance above what was expected so that OPOs would be held to the O:E ratio of the top performing OPOs. As previously discussed, we are not using the O:E measure because it is not capable of measuring volume, is directly correlated to the donation rate, and does not directly capture increases in organs being transplanted. Finally, adding this measure to the organ transplantation rate would introduce additional regulatory complexity and reduce the transparency of these outcome measures. Therefore, we are finalizing the organ transplantation rate as the second measure.

Final Rule Action: We are finalizing the definition of organ transplantation rate with revisions at § 486.302. The revised definition of ''Organ transplantation rate'' is the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs transplanted into patients on the OPTN waiting list as part of research are included in the organ transplantation rate. This modification is a clarification that if the organ is transplanted, regardless whether it is part of normal clinical practice or research, it will be counted in the organ transplantation rate. We are also making further modifications to the definition of ''organ transplantation rate,'' which are discussed in more detail in section II.B.7 of this final rule. We are also finalizing as proposed at § 486.318(d) that the OPO is evaluated by measuring the organ transplantation rate in their DSA.

5. Organ Definition (§ 486.302)

In the December 2019 OPO proposed rule, we specified how we would count the organs that would constitute the numerator for the organ transplantation rate. We proposed to include pancreata procured for islet cell transplantation and research in the definition of ''organ'' to meet the requirements of the Pancreatic Islet Cell Transplantation Act of 2004, which amended the PHS Act to include section 371(c). (84 FR 70631) Section 371(c) of the PHS Act states that ''[p]ancreata procured by an organ procurement organized and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b).''

Comment: Several commenters opposed our inclusion of pancreata for research in our outcome measures since procuring pancreata for research is not a normal function of OPOs and is highly dependent upon the demands of the local researchers. Some commenters supported the inclusion of pancreata procured and placed for research in the organ count. We received comments that including the pancreata for research would lead to artificial inflation of the organ transplantation rate; that we should use a third performance metric to assess performance for pancreata procured for research; and that we did not properly define the scope of ''pancreata procured for research.''

Response: We agree with the commenters that pancreata for research are specific to the local research demands and may not reflect universal OPO practice. Nonetheless, their inclusion in the outcome measures is consistent with the requirements of the statute, and we are finalizing them as such. We intend to verify the accuracy of the data reported related to pancreata procured for research during the survey process, and believe that this is a sufficient disincentive for inflating the reported data. We considered creating a third outcome measure specifically for pancreata procured for research. However, there is no data source currently available to enable us to analyze performance and establish a meaningful measure. We will continue exploring ways to develop a data source and meaningful measure for consideration in future rulemaking.

[9] 42 U.S.C. 273(b)(1)(D)(ii)(II).

[10] *https://www.srtr.org/about-the-data/guide-to-key-opo-metrics/opoguidearticles/donor-yield/.*

Comment: Commenters recommended CMS to include vascular composite allografts in the organ count for the organ transplantation rate.

Response: We appreciate this suggestion but are not including vascular composite allografts (VCA) in our definition of organ. VCA transplantation is very localized and rarely performed. In 2019, approximately 15 such transplants occurred, the vast majority being the transplantation of a uterus (12 transplants) [11]. Inclusion of VCAs as organs would require a separate assessment throughout all CMS policies and regulations that is beyond the scope of this rule.

Final Rule Action: After consideration of public comments, we are finalizing our proposed definition of organ at § 486.302 to mean a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation.

6. Donor Potential (§§ 486.302 and 486.318(d)(4))

Under § 486.318(d)(4), the donation rate, organ transplantation rate, and kidney transplantation rate use the ''Donor potential'' as defined under § 486.302 as the denominator. In our December 2019 OPO proposed rule, we proposed to define the donor potential (denominator) as total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that is not an absolute contraindication to organ donation. We proposed to use death certificate information that can currently be obtained from the Center for Disease Control and Preventions' (CDC), National Center for Health Statistics' (NCHS's) Detailed Multiple Cause of Death (MCOD) file as described in our December 2019 OPO proposed rule. The MCOD is published annually and is publicly available upon request. The MCOD comprises county-level national mortality data that include a record for every death of a U.S. resident recorded in the U.S. The MCOD files contain an extensive set of variables derived from the death certificates which are standardized across the 57 jurisdictions that provide CDC with the data (50 states, New York City, the District of Columbia and the five territories). The jurisdictions use the U.S. Standard Certificate of Death as a template for their forms.

In order to provide a most robust and detailed discussion, we have divided the comments and responses to our definition of ''Donor potential'' into separate sections: The use of state death certificates for estimating the donor potential; the specific ICD–10–CM codes used to identify the donor potential; the age threshold for the deaths; the inpatient aspect of the deaths; and the effect of waiver hospitals.

a. Death That Is Consistent With Organ Donation (§ 486.302)

Under § 486.302, within our proposed definition of ''Donor potential,'' we use a separately defined term, ''Death that is not an absolute contraindication to organ donation.'' This term is characterized by two major parts: (1) The data source for calculating these deaths (state death certificate data) and (2) the ICD–10–CM codes for identifying these deaths.

We proposed to use state death certificate information that can currently be obtained from the CDC, NCHS's MCOD file as described in our December 2019 OPO proposed rule to determine the donor potential. The MCOD is published annually and is publicly available upon request. The second part of the definition of ''Death that is not an absolute contraindication to organ donation'' describes all deaths except those identified by the specific ICD–10–CM codes listed in our definition that would preclude donation under any circumstance. As part of our proposed rule, we also considered the alternative of using the ICD–10–CM codes that are consistent with organ donation in the methodology developed by Goldberg, et al.[12] (84 FR 70662), also knowns as the ''CALC'' methodology.

We received numerous comments on both of these components and discuss responses to these comments separately.

i. Death Certificate Data

Comment: We received numerous and varied comments regarding our use of the death certificate information reported to the CDC and currently found in the MCOD files. Many commenters supported the use of data derived from death certificates because it represents the best available option for obtaining objective data at this time to estimate the donor potential. However, several commenters referenced literature that found error rates of the death certificates ranging from 30 to 60 percent. In addition, numerous commenters from the medical examiner/coroner community questioned the accuracy of the death certificates.

Response: We appreciate the commenters supporting our use of the MCOD file. As discussed in the December 2019 OPO proposed rule, we are aware of the error rates in the death certificate data reported in the literature, but continue to believe this data is the most complete information that is readily and publicly available, that can be used for estimating the donor potential at this time. Every state submits death certificate data to the CDC and the elements collected in the death certificates are standardized to the greatest degree possible. Errors in reporting on the death certificates are primarily from user error, where the individual completing the form makes a mistake. The same user errors likely plague other potential data sources, such as hospital records, and those data sources would come with significant added reporting burdens with limited to no additional benefit. We are not aware of differences in the error rates that would disadvantage one DSA over another DSA (84 FR 70632). In addition, we are not aware of any research that describes such differences. Based on our understanding of which professionals are responsible for completing the death certificates and comments from the public, we do not see a compelling reason why there would be a consistent disparity in the error rates from one DSA to another. Furthermore, no commenters have suggested a source of empirical evidence that could be obtained by reasonable effort of organ donor potential in each designated service area sufficient to meet our needs and expectations. The peer-reviewed research developed by Goldberg, et al. discussed throughout our December 2019 OPO proposed rule and this final rule supports the use of the death certificate data as the best and most comprehensive source for estimating the donor potential at this time.

We appreciate the comments and knowledge from the coroner/medical examiner community about the error rates in the death certificates.

Comment: We received one comment from the OPO in Alabama about errors in the electronic reporting of death certificate data resulting in misreporting inpatient deaths.

Response: We thank the commenter for pointing out the error in reporting inpatient deaths in Alabama. We understand that the reporting error has been resolved for 2019 and was unique to Alabama. We do not have any reason

[11] OPTN database accessed on July 11, 2020 and number of transplants for abdominal wall, head & neck (cranial facial), head & neck (scalp), GU: Penile, GU: Uterus, upper limb: Bilateral, upper limb: Unilateral, and VCA were counted for 2018 and 2019. In 2018, there were 11 transplants.

[12] Goldberg D, Karp S, et al., ''Importance of incorporating standardized, verifiable, objective metrics of organ procurement organization performance into discussions about organ allocation,'' *AmJTransplant.* 2019;00:1–6.

to believe that other states made this error. For purposes of the regulatory impact analysis in this final rule, which uses data from 2018, we have made adjustments to the inpatient deaths in Alabama to be more consistent with historical rates of inpatient deaths prior to the error occurring. If there are future occurrences in which there are similar such errors, we have added an extraordinary circumstances exception (ECE) under § 486.316(f) to allow OPOs to request a 1-year extension to their agreement cycle if there are extraordinary circumstances beyond the control of the OPO that would affect the data being used. This ECE request is discussed in greater detail in section II.C.5 of this final rule, which discusses the data length used for calculating the outcome measures.

Comment: We received a comment describing in detail the process by which the death certificate is completed in their particular state.

Response: We thank the commenter for providing us with this detailed information. States have slightly different processes for completing the death certificates even though all states use the standardized death certificates. The MCOD comprises county-level national mortality data that include a record for every death of a U.S. resident recorded in the U.S. The MCOD files contain an extensive set of variables derived from the death certificates which are standardized across the 57 jurisdictions that provide CDC with the data (50 states, New York City, the District of Columbia and the five territories). The jurisdictions use the U.S. Standard Certificate of Death as a template for their forms. Although commenters expressed concerns with our use of the MCOD, they did not suggest a different source of empirical evidence that could be obtained without undue reporting burden and was of greater accuracy. Furthermore, this commenter did not provide any information to suggest that this different process for their state would result in less accurate information for that jurisdiction and we do not have reason to believe that a different process would disadvantage one OPO compared to another.

Comment: We received a comment questioning whether our donor potential reflected the DSA because the publicly available CDC data on death certificates has the location of the death based on the individual's home rather than the location of the hospital.

Response: Based upon this comment, we believe that the commenter is referring to the CDC Wide-ranging Online Data for Epidemiologic Research (WONDER) database, which is available on the CDC public website. This database has the person's residence at the time of death instead of the location of the death. The MCOD file, which we are using to calculate our outcome measures, has information on the location (county) of the inpatient death. The location of the patient's death is more relevant to attributing donor potential for each DSA. A CMS contractor will use information from the MCOD file to attribute deaths to each DSA.

Comment: We received a comment that ''death certificate source is limited solely to statistical uses and cannot be used for regulatory purposes'' because section 308(d) of the PHS Act (42 U.S.C. 242m) provides that data collected by NCHS ''may be used only for the purpose of health statistical reporting and analysis.''

Response: We have consulted with the CDC and concluded that our use of the MCOD represents a statistical analysis to characterize OPO performance and is consistent with the PHS Act. We are not using the data from the MCOD file to directly take legal, administrative or other actions against the hospitals and states that submit the data, nor are we taking regulatory action on the inpatient deaths in the DSA. Rather, we are using the data to ''normalize'' our outcomes of interest: The number of donors and the number of transplants in the DSA. The section of the PHS Act cited by the commenter refers to the confidentiality of the NCHS data and the limitations of the use of the data if ''an establishment or person supplying the information or described in it is identifiable.'' Our calculations use county level data that does not identify the specific hospitals submitting the death certificate data.

Comment: We received comments that the death certificate data does not include information about co-morbidities or other chronic conditions that may make it unlikely for the person to be an organ donor.

Response: Our goal in using the death certificate data was to use the best information available to calculate organ donor potential in each DSA. We are using the death certificate data to adjust the denominator to better reflect the population in the DSA that will more closely resemble individuals likely to become a deceased organ donor (individuals who are 75 and younger and died in the hospital with a cause of death consistent with organ donation). No risk-adjustment method is precise and we do not have evidence that the rate of co-morbidities associated with these causes of deaths is significantly different from one DSA to another and would be the reason for the differences in performance.

Comment: Several commenters suggested alternative sources for estimating the donor potential: Data from electronic health records, data from hospital chart reviews, insurance billing codes, and hospital reported data of ventilated neurological deaths. Commenters also raised concerns about the burdens of asking donor hospitals to report potential donors and ventilated deaths, a concern that applies to all of the suggested alternatives.

Response: We thank the commenters for the suggestions of alternative data sources. All of the suggested data sources are subject to the same user error inaccuracies as the MCOD files. Furthermore, we note that none of these suggested alternative sources for estimating organ donor potential could be obtained by reasonable efforts and would not be feasible or practical for calculating the outcome measures. Many of the suggested data sources are not feasible to use or sufficiently comprehensive to estimate the donor potential for various reasons. First, not all hospitals have electronic health records that can transmit data or be shared; not all OPOs have the ability to receive electronic health record transmissions. Second, collecting data via hospital chart reviews would likely be burdensome. Third, there is no national or comprehensive database of all insurance claims, and collecting data from insurance claims would inappropriately not count those decedents who did not have insurance. We agree with those comments that raised concerns about the burden on donor hospitals if we asked them to report data on ventilated deaths, and agree that requiring those additional reporting requirements or combining all these disparate data sources to estimate the donor potential could not be obtained by reasonable efforts. CMS will continue to evaluate the benefit and applicability of future data sources as they become available.

Final Rule Action: We are finalizing the death certificate information reported to the CDC and currently found in the MCOD files as the data source for calculating the donor potential of each DSA.

ii. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM)

Comment: The vast majority of comments supporting the use of the state death certificate data from the CDC files also preferred using ICD–10–CM codes that represented the causes of

death that is consistent with organ donation rather than our proposed approach based on defining ''death that is not an absolute contraindication to organ donation.'' Some commenters suggested adding other ICD–10–CM codes to the list of ICD–10–CM codes we would exclude. One commenter stated that the ICD–10–CM codes consistent with organ donation provided a donor potential that was consistent with their own internal calculations. Another commenter provided an estimate of 187,500 donor referrals in the U.S. based on extrapolation of their own data.

Response: Given the overwhelming comments supporting the use of the ICD–10–CM codes from the methodology which is based on the cause, age, and location consistent with organ donation (CALC), we are finalizing the use of ICD–10–CM codes from the CALC methodology, which are inclusion codes, in estimating the donor potential. Our proposed methodology used the ICD–10–CM codes that are exclusion criteria and included significantly more codes. The ICD–10–CM codes that are considered as causes consistent with organ donation were identified in section V.G ''Alternatives Considered'' of the December 2019 OPO proposed rule, and were confirmed by the developers of the CALC methodology, although they were not specified in the published literature. As discussed in the December 2019 OPO proposed rule, the ICD–10–CM codes in the CALC methodology captures 98–99 percent of all donors. (84 FR 70666). The advantage of this inclusion method over the one we proposed is that given the description of the ICD–10–CM codes chosen, there are unlikely to be new causes of death that would lead to organ donation. However, as we have discovered during the COVID–19 public health emergency (PHE), there is a likelihood of new, unanticipated contraindications for organ donation. If we used exclusion criteria in estimating the donor potential, we could have to update and change our rules much more frequently to adjust for these new contraindications to organ donation. We believe that these unplanned changes could be disruptive to OPO operations and efficiency. Therefore, we agree with commenters that the CALC methodology which identifies ICD–10–CM codes consistent with organ donation is preferable to the methodology we proposed. We discuss this methodology and the calculations that result from using this methodology in greater detail in the discussions of our regulatory impact analysis under section V of this final rule.

In § 486.302, we have added the definition ''Death that is consistent with organ donation'' as all deaths from the state death certificates with the primary cause of death listed as the ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–1–Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation. From our calculations using 2017 data, the CALC methodology resulted in a donor potential of 101,479, which would be a reasonable estimate of the total U.S. donor potential if the donor referral is approximately 187,500 as suggested by a commenter who estimated this donor referral population based on their own referral data.

We also conducted preliminary analyses examining whether there was additive value to excluding the ICD–10–CM codes that were contraindications to organ donation to the causes of death that is consistent with organ donation. We found little difference in the ranking and identification of OPOs at the different thresholds of interest. Therefore, we are not using any ICD–10–CM codes to exclude additional inpatient deaths from the ICD–10–CM codes that are consistent with organ donation.

Comment: We received several comments questioning the donor potential and providing references that cited donor potential varying as low as 10,500 and as high as 272,000 (our estimate).

Response: We know the donor potential cannot be as low as 10,500 because there were 11,870 deceased donors in 2019, according to the OPTN (*https://optn.transplant.hrsa.gov/news/organ-donation-again-sets-record-in-2019/*). Our ''donor potential'' was not designed to identify an actual donor potential size as we have discovered that the true donor potential changes constantly as technology and demand for organ transplantation changes. Instead, our proposed methodology was designed to estimate the likely donor referral population to normalize the inpatient deaths across the different DSAs. Since the donor potential is part of a rate calculation, identifying the exact, true donor potential is less relevant than providing standardized, reasonable, and objective criteria to estimate it. We know that as public health crises occur, such as the opioid crisis or COVID–19, the donor potential may change. Also, as technology and practices change, the donor potential may change. When the 2006 OPO final rule was published, DCD was so infrequent that those potential donors were not included in the definition of an eligible death; yet in 2019, almost 23 percent of all deceased donors were DCD donors. Based on public comments, we believe the CALC methodology produces a very close estimate to the current donor potential for each DSA and it also has the flexibility to adjust to changes in the number of these causes of death in the DSA.

Final Rule Action: We are finalizing under § 486.302 that ''Death that is consistent with organ donation'' means all deaths from state death certificates with the primary cause of death listed as the ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–1–Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation. We will not include in the final rule a definition of ''death that is not an absolute contraindication to organ donation.''

b. Age 75 and Younger

Comment: We received comments that the proposed age cut-off of age 75 in our definition of ''donor potential'' was too high and suggested that we should use age 65 instead. On the other hand, we also received a comment that the proposed age cut-off of age 75 was too low because OPOs have procured livers from donors older than 75.

Response: We proposed that the denominator for calculating the donation and organ transplant rates will be based on the number of inpatient deaths of someone 75 years old or younger because our previous definition of eligible death uses the age of 75 years old or younger. We do not concur with commenters' suggestion to lower the age threshold for the donor potential for our new outcome measures. Although we are aware that it is possible to for liver donors to be older than 75 years of age, we also recognize that the practice of using organs from older donors is still relatively new. Data from the OPTN lists the maximum age of liver donors as 65+. The number of living donations from this group between 2014 and 2019 ranged from 571 to 732 with gradual increase over time.[13] It is, however, a practice we want to encourage in order to increase the number of successful transplants; therefore, we are keeping our age limit at 75 years in order to reward OPOs who are successful with the donation and transplantation of organs from deceased individuals

[13] *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/.*

greater than 75. OPOs who are successful in procuring these organs, particularly livers, from older donors may be able to count the donors and organs transplanted in the numerator of our outcome measures without having the death counted in the denominator.

Final Rule Action: We are finalizing that the age cutoff of age 75 for the donor potential definition in § 486.302, as proposed without modification.

c. Inpatient Deaths

We did not receive any comments as to whether the deaths should be limited to inpatient deaths. We are aware of preliminary studies suggesting that potential donors are identified in the emergency department as well as the inpatient setting. However, we believe those individuals are likely to become inpatients and thus, the location where they are identified, may not always correlate with where they die. Our data source is based on the location of death.

Final Rule Action: We are finalizing that the definition of donor potential under § 486.302 be limited to inpatient deaths.

d. Waiver Hospitals

Comment: We received a number of comments inquiring how CMS is addressing the donor potential estimates in DSAs where some donor hospitals sought waivers to work with a different OPO. One commenter raised concerns that we made an error in calculating the donor potential because we assigned the donor potential to the wrong OPO.

Response: Historically, DSAs have been divided based on counties and metropolitan statistical areas. However, donor hospitals can request the ability to work with an OPO outside their DSA through a waiver request (we refer to these donor hospitals as ''waiver hospitals'' under § 486.308(e)). In estimating the donor potential for each DSA, we relied on the listing of counties found in the SRTR's OPO-specific reports, which listed both counties to an OPO when more than one OPO was servicing the county because of the waiver hospital. As a result, we erroneously double-counted the donor potential in several DSAs in the December 2019 OPO proposed rule. This inaccurate ranking would not have significantly altered our projections of the number of OPOs that would be automatically certified or decertified in accordance with the measure parameters set forth in the proposed rule.

While there are no data sources which we can use to precisely attribute non-Medicare inpatient deaths to these waiver hospitals, we can apportion the donor potential to each OPO by calculating the percentage of Medicare inpatient deaths at each acute care and critical care hospital in the county as a proxy, and use that percentage to divide the donor potential and assign the percentage of the donor potential based on the Medicare percentage of inpatient deaths. At this time, the apportionment method we have described is the best solution to addressing donor potential for OPOs that work with waiver hospitals. We intend to explore other options that could improve the data about deaths that should be counted for waiver hospitals.

Final Rule Action: In response to public comments, we are amending the definition of the donor potential at § 486.302 to apportion the donor potential in a county where there is a donor hospital that has received a waiver to work with an OPO out of their DSA. For OPOs servicing a hospital with a waiver under § 486.308(e), the donor potential of the county for that hospital will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county.

7. Risk-Adjustments §§ 486.302 and 486.318(d)(2)

In the December 2019 OPO proposed rule (84 FR 70628), we did not propose other risk-adjustments to the proposed outcome measures, but sought comments as to the accuracy of our assessment and whether additional risk adjustments were necessary. We sought comments on whether risk-adjustments are necessary and which ones, such as donor demographic characteristics (race, gender, age, disease condition) or DSA characteristics (number of ICU beds or level I and II trauma centers) would be significant and clinically appropriate in the context of our proposed approach to identifying OPOs in need of improved performance. Specifically, we requested public comments that provide evidence-based support, such as peer-reviewed literature, that would support those suggestions, as well as data sources that would be necessary to calculate the risk-adjustments recommended.

a. Chronic Diseases

Comment: We received comments from some OPOs about the incidence of certain diseases in their DSA that would make their general population less likely to be organ donors or have more organs available for transplantation. We received comments describing the different incidences of diseases in the different parts of the country.

Response: We appreciate the comments about the different incidences of disease in the different geographic areas and recognize that different DSAs may have different population characteristics. However, these differences are population-based differences, and we did not receive any data that these differences were reflected in the donor potential, resulting in a disadvantage to one OPO compared with other OPOs. As part of our proposed rule, we analyzed whether there was a correlation between the performance of the OPO and the number of patients on the waiting list in the DSA (84 FR 70633). We conducted the analysis to determine whether ''demand'' in the form of the number of patients on the waiting list for the transplant centers within the OPO's DSA, is correlated with performance. We did not find any correlation. We reviewed the original analysis to determine whether there was a negative correlation between the waiting list and OPO performance (that is, OPOs flagged were more likely to have a sicker population in its DSA). Here, we treated the waiting list as a surrogate for the magnitude of end-stage organ failure in the DSA. Again, there was no correlation between OPO performance and end-stage organ failure in the DSA. As discussed earlier, we had compared using just the CALC versus the CALC plus our exclusionary criteria. There was no additive value to removing these contraindications to organ donation.

Comment: One commenter suggested that we use data from the U.S. Renal Data System (USRDS) to risk-adjust for chronic kidney disease because people with chronic kidney disease are less likely to be organ donors.

Response: Although we examined the USRDS data, we did not consider using it to risk-adjust for chronic kidney disease because it is population data and does not necessarily reflect the donor potential. Furthermore, the USRDS data does not delineate the different levels of chronic kidney disease. People with early stage chronic kidney disease can donate extra-renal organs for transplantation as well as the kidneys.

b. Race

Comment: We received several comments from OPOs describing the racial/ethnic characteristics of people in their DSA and claiming that if we risk-adjusted for race, their performance would be improved because they serve a smaller percentage of white people than the national average. We also received comments opposing risk-adjustments based on race because of

concern that these risk-adjustments would mask past poor performance in adopting practices that are responsive to the racial/ethnic composition of the DSA served.

Response: As we stated in our December 2019 OPO proposed rule, we decided not to risk-adjust for race because of concerns that it reflects historically poorer performance with certain racial/ethnic populations, and that studies suggest that OPOs can adopt policies and practices responsive to the community they serve and have better results. When we assess OPO performance, as seen in Table 3 in our regulatory impact analysis of this final rule, we see a diversity in the population served by the highest performing OPOs. We also see poor performance among OPOs servicing predominantly white populations. We agree with commenters who raise concerns that risk-adjusting for race could mask poorer performance, and we have concerns that racial risk-adjustments could perpetuate the stereotypes of different racial/ethnic groups and their willingness and ability to be organ donors.

We have reviewed the analysis conducted by the SRTR implying that racial risk-adjustment would ensure that a ''correct'' decision is made when comparing OPO measures.[14] We do not find these analyses compelling since the risk-adjustments reflect the biases and shortcomings of current OPO organ procurement practices, and we are not aware of a biological reason why race, as an independent factor, would affect the decision to be an organ donor or the number of organs transplanted. We agree with public comments and other literature opposing risk-adjustments for race.[15] We believe OPOs should be adjusting their practices to meet the characteristics of the DSA. Based on the diverse populations serviced by the top performing OPOs, we believe that racial characteristics of the DSA should not be a reason for risk-adjusting OPO performance.

Although one of our previous outcome measure (the O:E measure) includes multiple risk-adjustments, such as for race, we are not including racial risk-adjustments in our final rule. The literature since 2005 (described in the December 2019 OPO rule), the public comments we received, and our examination of the demographics of the top performing OPOs, suggest that these factors, while they potentially pose hurdles for each OPO in their DSA, they are insufficient justification for additional risk adjustment. Therefore, we expect all OPOs to adjust their practices to overcome these hurdles and best service the populations within their respective DSAs.

c. Gender and Age

Comment: We received comments that we should risk-adjust for identifiable variables in the donor potential data such as gender and age.

Response: We do not know of a biological basis for why gender would be an independent factor in predicting the likelihood for being an organ donor or the number of organs transplanted.

We do, however, agree that there is biological basis for age to predict the likelihood of being a donor and the number of organs transplanted from the donor potential. Our internal analysis found statistically significant differences in the average age of the donor potential when we ranked OPOs based on their outcome measures, suggesting that age has an effect the number of donors and organ that are transplanted.

Since we are already including the age cut-off of 75 years and younger in our donor potential, we do not intend to further risk-adjust the donation rate for age. It is possible that the differences we see in performance based on the average age of the donor potential reflects OPO biases against older potential donors. Further risk-adjustments could mask these biases. Based on our methodology, in the DSAs where the population is older, OPOs have the opportunity to perform better because they have more opportunities for a donor who is older than 75 years of age—and these donors count in the numerator, but not in the denominator.

For the organ transplantation rate, there is no current risk adjustments for the average age of the donor potential. Our own internal analysis found that the average age of the donor potential correlated with performance on the organ transplantation rate, we will risk-adjust the organ transplantation rate based on the average age of the donor potential using the following method, provided here for full transparency and to allow others to replicate our methodology and calculations:

1. The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

2. Calculate a national age-specific transplantation rate for each age group. An expected transplantation rate for each OPO is calculated as **Σ**(g=1) Gdg*Rg/**Σ**gdg,[16] where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific national transplantation rate in age group g, and **Σ**gdg is the OPO's total number individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

3. Calculate the age-adjusted organ transplantation rate as (O/E)*P, where O is the OPO's observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

d. Ventilator Status

Comment: We received comments stating that there were differences in ventilators in ICUs based on geography, and that including ventilator status would be important in deriving the donor potential.

Response: While there are differences in ventilators in ICUs based on geography, we do not have evidence that additional information about ventilator use would improve the CALC methodology. Since publication of our proposed measures, there has been a published study confirming our analysis that additional adjustments on cancers, sepsis and ventilator status to the CALC measure does not alter the ranking of OPO performance.[17]

Final Rule Action: We are finalizing with modification the definition of ''organ transplantation rate'' at § 486.302 to be risk-adjusted for the average age of the donor potential using the following methodology:

(1) The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

(2) Calculate a national age-specific transplantation rate for each age group. An expected transplantation rate for each OPO is calculated as **Σ**(g=1)Gdg*Rg/**Σ**gdg, where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific national transplantation rate in age

[14] Snyder JS, Wey A, et al., ''The Centers for Medicare and Medicaid Services' proposed metrics for recertification of organ procurement organizations: Evaluation by the Scientific Registry of Transplant Recipients,'' Am J Transplant, 11 Mar 2020.

[15] Goldberg D, Doby B, Siminoff L, et al., ''Rejecting bias: The case against race adjustment for OPO performance in communities of color,'' Am J Transplant, 2020;00:1–6.

[16] **Σ** is a mathematical symbol indicating summation.

[17] Goldberg DS, Doby B, Lynch R, ''Addressing Critiques of the Proposed CMS Metric of Organ Procurement Organ Performance: More Data Isn't Better,'' Transplantation; 2019 Nov 26.

group g, and **Σ**gdg is the OPO's total number of individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

(3) Calculate the age-adjusted organ transplantation rate as (O/E)*P, where O is the OPO's observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

We are also finalizing at § 486.318(d)(2) that the organ transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. The organ transplantation rate is adjusted for the average age of the donor potential.

8. OPO Performance on Outcome Measures § 486.318(e) and § 486.302

In our December 2019 OPO proposed rule, we proposed to use our outcome measures in the context of a comparative donation rate and organ transplantation rate relative to the highest-performing OPOs. Our proposed definition of success would have been based on how OPOs perform on the outcome measures of donation rate and organ transplantation rate compared with the top 25 percent of donation and transplantation rates in DSAs with the goal of driving all OPO performances to cluster with the top performing OPOs. We proposed that OPOs would be assessed annually on these outcome measures and those whose outcome measures were below the top 25 percent would need to revise their QAPI to improve their performance. In the final year of the re-certification cycle, we proposed that OPOs whose outcome measures were below the top 25 percent will have failed their outcome measures for purposes of re-certification. We proposed to generate a one-tailed confidence interval for rates in each DSA to determine whether the OPO's outcome measures were statistically significantly the same or above the threshold rate of the top 25 percent. The top 25 percent rate would be generated using the rates established in the prior assessment period.

It is important to note that the outcome measures requirement does not require an OPO's performance be at or above the lowest rate for the top 25 percent of all of the OPOs. By determining confidence intervals, there is a range of values and the OPOs must not be statistically significantly difference from that range of values. For example, there are currently 58 OPOs. For the 58 current OPOs, twenty-five percent would be 15 OPOs (58 × .25 = 14.5). However, as discussed below, based on 2018 data, we estimate that 24 OPOs would meeting the criteria in § 486.318 to be designated as a Tier 1 top performing OPO.

We solicited public comments on whether or not comparing OPO performance should be based solely on the performance of the top 25 percent of OPOs within these two outcome measures, whether a different percentile or calculation of OPO performance should be used, or whether additional outcome, structure, or process criteria could be used to inform stakeholders of OPO performance over time (84 FR 70634).

The comments and responses are below.

Comment: We received a diversity of comments in response to our proposed approach of establishing a threshold rate at the top 25 percent performance for OPOs to achieve. Some commenters supported our aggressive threshold rate of performance to drive an increase and improvement in OPO performance.

Response: We thank the commenters who support our aggressive threshold rates. We intend to finalize, as proposed at § 486.318(e)(4) that OPOs whose donation rate and organ transplantation rate in the DSA is statistically significantly at or above the top 25 percent threshold rate will be considered have met the outcome measures for re-certification and their top performance will be recognized with a Tier 1 assignment. As a Tier 1 OPO, they will be rewarded by not being required to revise their QAPI to improve their performance in the outcome measures and their DSAs will not be opened for competition at the end of the re-certification cycle as long as they meet the other Conditions for Coverage during the re-certification survey.

Comment: We received comments suggesting alternative threshold rates such as 50 percent or a tiered approach to ranking OPOs with different changes that must occur based on where the OPO falls in the tier system.

Response: We thank the commenters for these suggestions. As we stated in the discussions of our alternatives in the December 2019 OPO proposed rule, we considered using a threshold rate based on the median or the geometric mean, but were concerned that this lower threshold rate would not incentivize OPOs to be higher performing. Furthermore, we ran the risk of top performing OPOs not being sufficiently incentivized to maintain their current performance level if we did not use an aggressive rate.

However, we also recognized that our aggressive threshold rate could result in too many OPOs being de-certified, particularly in the first re-certification cycle, without enough OPOs with organizational capacity and interest to assume responsibility for those open DSAs. We also recognize that if we set a threshold rate too difficult to attain, we risked incentivizing poorer performing OPOs to not strive to improve while remaining certified for a full 4-year cycle. Therefore, we are modifying our proposal and finalizing a 3-tier system based on public comments whereby OPOs are stratified into different tiers based on their outcome measures. The consequences of being in each tier differ based on whether the performance occurs as part of the annual assessment or if it occurs during the final assessment period. OPOs in Tier 1 are the OPOs that would have reached the goal performance of the top 25 percent threshold rates. We consider these OPOs to be top performing Tier 1. Based on data from 2018, we estimate that 24 OPOs would be in Tier 1.

The next tier will be identified as Tier 2 and will include OPOs in which both measures, donation rate and organ transplantation rate, have reached the median threshold rate or above (but are not in Tier 1). We estimate that there are 12 OPOs that would fall into Tier 2 based on 2018 data. Tier 2 OPOs will be considered to have met the outcome measures under § 486.318, and would not be decertified, but these OPOs will not be automatically re-certified. Since they have not reached the outcome measure requirements for Tier 1 status, their DSAs will be opened for competition and they will have to compete to retain their DSAs. Greater details about the competition process are discussed in section II.C of this final rule.

And finally, the lowest tier will be identified as Tier 3 and will include OPOs who have one or both outcome measures that are statistically significantly below the median threshold rates. We estimate that there are 22 OPOs who fall into Tier 3 based on 2018 data. Tier 3 OPOs will be considered as failing the outcome measures and will be de-certified. Greater details about the competition process are discussed in section II.C of this final rule.

This 3-tier system was designed based on a combination of comments that we use the 50 percent threshold rate instead of the top 25 percent threshold rate and the comments to use a tier system with varying consequences to OPOs based on the tier they were in. Instead of using a 50 percent rate or a mean rate, we chose

the median rate because both the top 25 percent threshold rate and the median rate represent the actual rates performed by one or two OPOs (when there is an even number, the median is calculated by averaging the two rates in the median). The mean rate, on the other hand, is a mathematical rate that may not reflect the performance of an actual OPO. A median, however, is not affected by extremes in performance. By identifying a specific rate of an OPO, other OPOs can directly compare their performance with another OPO.

Our goal in creating these tiers is to reward the top performing OPOs (Tier 1), while giving OPOs in Tiers 2 and 3 sufficient incentives to improve their performance and achieve ranking in the next level up and give Tier 2 OPOs the opportunity to demonstrate that they deserve to retain their DSA. These rewards and incentives are described in greater detail in this section and in our discussion about competition in section II.C of the final rule and our regulatory impact analysis (RIA).

Comments: We also received comments that the 25 percent threshold rate was too aggressive and too many OPOs would be de-certified (discussed in detail at section II.C of this final rule), resulting in chaos in the system. Some commenters suggested that if we were to use such an aggressive threshold rate, we should not automatically de-certify OPOs who did not meet the threshold rates. Instead, we should consider a systems improvement agreement (SIA) similar to the ones for transplant program or the substantial changes they have made as part of their QAPI to avoid the disruption from de-certifying the OPO. In contrast, we received a comment that despite our aggressive threshold rate for performance, we should implement outcome measures that continually drive all OPOs to improve their performance.

Response: We agree with some of the comments relating to a tiered approach. OPOs are not automatically decertified the first time that they do not meet the threshold rates. The performance of each OPOs will be assessed annually, this information will be provided to each OPO, and each OPO will then have an opportunity to improve and receive information about its performance following those improvements. Our annual outcome assessment is designed to inform the OPO regularly about their performance. Therefore, OPOs identified as being lower performing at the final assessment period of the agreement cycle would have a history of working with CMS to improve performance, as they would have been provided with their own performance information and making adjustments to their QAPI to improve their performance in the previous assessment periods. We expect to provide notice to OPOs of their performance and make the results public within 15 months of the end of each assessment period. For instance, performance on data from 2020 will be provided to OPOs and made public by the end of the first quarter in 2022. This period is necessary to accommodate the timeframe for the CDC to process the data and make the MCOD available for public use as well as for CMS calculate the performance measures. Additionally, during this timeframe, CMS will share preliminary results with each OPO to provide the opportunity to review the information and raise any concerns prior to the results being made publicly available and taking any enforcement action. This preliminary review is consistent with past performance updates and while this is an informal process, it does afford each OPO the opportunity to address concerns regarding its results. We acknowledge the time lag in making this information available, however, all data sources have inherent delays in making their information available to the public. Additionally, OPOs should not be relying on any single source of information to conduct self-assessments of their performance and should be employing a variety of information as part of a comprehensive QAPI program for this purpose.

We are not adopting public comments suggesting that poorly performing OPOs should be permitted to continue under an SIA. Allowing poorer performing OPOs the opportunity to continue servicing the DSA through a SIA would not benefit patients if there is a better performing OPO willing and able to service the DSA and provide patients with a higher standard of service.

However, we recognize that there are some OPOs that fall below Tier 1 but have made substantial changes designed to improve performance and have started to improve their performance. It may not be in our or patients' best interest to de-certify those OPOs, unless there is a better OPO prepared and capable of taking over the DSA. Thus, we created Tier 2 in response to the comments that we should lower our threshold rate for performance, and should not automatically de-certify OPOs who cannot reach Tier 1.

The commenter who suggested the tier system proposed that we undertake certain administration actions (like require change in leadership) based on the OPO's tier. While we appreciate the suggestions, we do not believe that there is a one-size fits all approach for all the OPOs in Tier 2, or that the federal government should dictate the specific steps needed to increase the rates in a particular DSA. Based on our assessment of outcome measures for these OPOs in Table 3, the range of performance is quite varied, with some OPOs very close to Tier 1 and others at the bottom of Tier 2. We are reluctant to follow the comments suggesting that OPOs be given an opportunity to continue as the designated OPO for another cycle subject to an SIA. That suggestion assumes that all OPOs in Tier 2 are capable of improving their performance and that they just need more time to implement best practices and improvements. However, because all OPOs receive interim reports on performance levels, we do not agree that this is always the case. Moreover, we recognize that patients in the DSA well-served by a marginal OPO that is allowed to continue without facing competition from a high performing OPO. Requiring that OPOs in Tier 2 to engage in a competitive process with other interested OPOs, on the other hand, would incentivize continual improvement to the benefit of patients.

Section 1138(b) of the Act and section 371 of the PHS Act required that the Secretary establish performance and outcome measures to be able to evaluate an OPO's performance prior to recertification. Requiring that Tier 2 OPOs compete for their DSA incentivizes best practices and optimizes organ donation and transplant rates. As already discussed and proposed, OPOs whose rates in the DSA fall under Tier 1 are considered to have met the outcome measure requirements and their DSA is protected from competition. OPOs identified as being in Tier 3 are considered to have failed the outcome measures under § 486.318 and will be de-certified, and following any administrative appeals, their DSAs will be open to competition.

Instead of automatically de-certifying OPOs in Tier 2 (those who have a statistically significant donation and organ transplantation rate at or better than the median rate) or implementing an SIA, we will allow these OPOs to compete to retain their DSAs by opening their DSA for competition to all OPOs that have been identified as being in Tier 1 and 2. In summary, all the DSAs for OPOs identified in Tiers 2 and 3 will be open for competition as proposed in our December 2019 OPO proposed rule and all the OPOs who are identified in Tier 1 and 2 will be able to compete for an open DSA. Broadening the number of DSAs open to competition and the number of OPOs eligible to compete will result in greater improvements

among all OPOs. OPOs in Tier 1 will need to maintain or improve their performance if they want to successfully compete to take over a new DSA, and OPOs in Tier 2 will need to improve their performance to retain their DSA or takeover another open DSA. Since OPOs identified under Tier 2 would have been de-certified under our original proposed methodology, this new approach will give mid-performing OPOs, who otherwise would have been de-certified, the opportunity to demonstrate, through the competition process, that they have implemented the requisite changes to progress to becoming a Tier 1 OPO.

Because OPOs have a 4-year exclusive agreement for each DSA with each re-certification cycle (see § 486.308(a)), it is critical that we select the most capable OPO that we can find to service the area, rather than automatically re-certify the incumbent OPO in Tier 2 or trying to ''fix'' an OPO that has not been able to reach the same performance as the top performing OPO through an SIA. We believe a competition process whereby all OPOs have sufficient incentives to continue to improve will drive all OPOs to cluster near the top.

Comments: We also received many comments suggesting we use a standard deviation from the mean because it was statistically superior.

Response: We disagree with the comments that the standard deviation from the mean methodology is statistically superior for our purposes of calculating OPO performance measures.

Under our methodology, all OPOs have the opportunity to cluster at the top because we generate confidence intervals for their donation and organ transplantation rates. The threshold rate is based on the previous year's rate and represents a specific rate to achieve or exceed. If all the remaining OPOs (below the top 25 percent threshold rate) had rates close to the threshold rate, their confidence interval could have all of them equal or exceed the threshold rate, resulting in clustering near the top. In Table 3, we show that 24 of 58 OPOs meet the top 25 percent threshold rate and this is 41 percent of all OPOs.

The standard deviation from the mean method, on the other hand, generates a list of OPOs that are a certain distance from the mean. As we discussed earlier, the mean is problematic because several lower performing OPOs could skew the calculated mean. The mean and the standard deviations are also generated contemporaneously with the ranking of the OPOs, giving OPOs no notice of their targeted performance. And, by nature of the statistical method of standard deviation, there will always be an OPO below the targeted standard deviation from the mean, meaning that not all OPOs would have the opportunity to be a top performing OPO unless they all had identical rates.

Comments: We received comments implying that our goal was to reduce the number of OPOs and our methodology would result in an ever increasing threshold rate and ever-shrinking number of OPOs after each cycle.

Response: We understand the concerns expressed by these comments, and want to reassure the public that our goal is to improve oversight of OPOs by reducing the variability in performance among OPOs and in the DSAs, not necessarily reducing the number of OPOs or forcing consolidation. Our methodology allows all OPOs the opportunity to perform as well as the top OPOs. We have proposed to change the outcomes measures because we agree with the public comments that the current OPO outcome measures are not sufficiently objective and transparent to ensure public trust in assessing OPO performance, nor do they properly incentivize the adoption of best practices and optimization of donation and organ transplantation rates.

Our methodology may result in increasing the threshold rate without shrinking the number of OPOs or DSAs significantly. Our internal analysis reveals demonstrated improvements in OPO performance from 2017 to 2018 and we anticipate OPO performance will continue to improve when incentivized by more transparent and accountable measures provided under this final rule. But, we recognize that there may be a rate at which OPOs cannot improve anymore and rates may cluster at the top. However, we intend to incentivize increases in the threshold rates for the top 25 percent and median as it would indicate that OPOs are procuring more organs for transplantation. Our methodology does not presume or require an increase in the threshold rates, and accounts for the performance of OPOs under similar circumstances or extraordinary circumstances.

In order for there to be an ''ever-increasing threshold rate and ever-shrinking number of OPOs,'' the commenter assumed that we would require that DSAs merge when an OPO takes it over. Our methodology for assessing OPO performance is based on the outcome measures for the OPO in each DSA. In our December 2019 OPO proposed rule (84 FR 70636), we stated that our regulations do not require that DSAs merge when a new OPO takes over. It would be our preference to not merge DSAs so that we can properly assess whether the new OPO is improving performance in each DSA since merging DSAs would result in merging the data on performance. Since DSAs are not required to merge, one OPO could run several DSAs. If an OPO with multiple DSAs cannot reach the outcome measures to be re-certified for one DSA, they will be de-certified for that DSA, but could be re-certified for other DSAs (assuming their performance supports it). Using our estimates from 2018 data, the result after conclusion of the first certification cycle that implements the new measures (2022–2026) could be approximately 36 OPOs servicing 58 DSAs with reductions in OPOs but not in DSAs. With 58 DSAs being served by top performing OPOs each cycle, we would expect the threshold rate to increase until all DSAs have donation and organ transplantation rates that cluster near the top. Even if consolidation were to occur in the industry, we believe that the certification process would retain a sufficiently large number of OPOs s to maintain an adequately diversified market in U.S.

Comment: We received some comments that our threshold rate of 25 percent was arbitrary. We also received comments pointing out parts of the country where no OPO was top tier such as the New England area or the Gulf Coast.

Response: We respectfully disagree with the commenter that our proposed threshold rate was arbitrary. It was chosen to mathematically achieve the Secretary's goal of doubling kidney transplants by 2030. It was also chosen because, when we assessed which OPOs were top performing, we found that that threshold rate of 25 percent provided us a diversity of OPOs serving a range of geographic areas and different donor potentials. The 25 percent threshold rate and our inclusion of a confidence interval was chosen to accommodate any uncertainty about what constitutes a top performing OPO.

In our December 2019 OPO proposed rule, we presented maps stratifying OPO performance in quartiles. The purpose of these maps was to show that even though many OPOs did not meet the threshold rate, they were quite close. Our current data analyses in Tables 1 through 3 also show that it is likely achievable for many more OPOs to reach the Tier 1 threshold rates. Additionally, our internal analysis indicates that the number of OPOs historically achieving Tier 1 status increased from 16 in 2017 to 24 in 2018, without any regulatory incentives, demonstrating that OPOs have the ability to improve their performance.

Comment: We received a comment that the 95 percent confidence intervals (CI) were biased against large OPOs because they would likely have a narrow interval.

Response: The purpose of the confidence interval was to ensure that the use of the threshold rate does not bias against small OPOs who may be prone to greater variability of rates due to smaller volumes. We do not concur with the commenters' assertion that our methodology is biased against large OPOs; they have a CI generated, but because they have more data, their CIs are proportionally smaller.

We did not receive any comments on the proposed mathematical methodology which we use to calculate the ''Lowest rate among the top 25 percent'' or the time period in which the rate will be calculated. Thus, we will be finalizing as proposed that the threshold rates for the donation and organ transplantation rates would be based on the 12-month period immediately prior to the period being evaluated and finalizing the definition of the Lowest rate among the top 25 percent with technical edits to clarify that the rate is based on the donation and organ transplantation rates in the DSAs.

Final Rule Action: Under § 486.302, we are finalizing as proposed the definition that the ''Lowest rate among the top 25 percent'' will be calculated by taking the number of total DSAs in the time period identified for establishing the threshold rate. The total number of DSAs will be multiplied by 0.25 and rounded to the closest integer (0.5 will round to the higher integer). The donation rates and organ transplantation rates in each DSA will be separately ranked and the threshold rate will be the rate that corresponds to that integer when counting down the ranking.

We are finalizing § 486.318(e) with revisions, that (1) For each assessment period, threshold rates will be established based on donation rates during the 12-month period immediately prior to the period being evaluated: The lowest rate among the top 25 percent in the DSAs (paragraph (e)(1)(i)), and the median rate among the DSAs (paragraph (e)(1)(ii)) and, (2) For each assessment period, threshold rates will be established based on the organ transplantation or kidney transplantation rates (as applicable) during the 12-month period prior to the period being evaluated: The lowest rate among the top 25 percent in DSAs (paragraph (e)(2)(i)), and the median rate among the DSAs (paragraph(e)(2)(ii)).

We are finalizing as proposed at § 486.318(e)(3) that the 95 percent confidence interval for each DSA's donation and organ transplantation rates will be calculated using a one-sided test.

In response to public comments, we are finalizing § 486.318(e)(4) through (6), the creation of three tiers to identify OPO performance.

Tier 1—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the top 25 percent threshold rate established for their DSA will be identified at each assessment period.

Tier 2—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the median threshold rate established for their DSA but is not in Tier 1 as described in paragraph (e)(4) will be identified at each assessment period.

Tier 3—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation or organ transplantation rates that are below the median threshold rate established for their DSA will be identified at each assessment period. OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are below the median threshold rate for their DSA are also included in Tier 3.

9. Non-Contiguous States, Commonwealths, Territories, or Possessions § 486.318(e)(7)

In the December 2019 OPO proposed rule (84 FR 70628), we did not propose different outcome measures for OPOs exclusively serving non-contiguous states, commonwealths, territories, or possessions because we believe that OPOs servicing those areas should perform at the same level as the top 25 percent of OPOs. That being said, we sought comments on the burden and unique challenges that may face OPOs in the noncontiguous states, commonwealths, territories, or possessions, and whether using just the kidney transplantation rate for the Hawaii OPO would be an appropriate measure of performance as discussed in section V.G ''Alternatives Considered'' of the December 2019 OPO proposed rule.

Comment: We received numerous comments in support of using a different standard for OPOs exclusively serving non-contiguous states, commonwealths, territories, or possessions. Both the Hawaii and Puerto Rico OPOs submitted comments describing the difficulty in placing extra-renal organs because of the geographic hurdles.

Response: Based on information from the commenters regarding the unique geographical challenges of the OPO servicing the Hawaii DSA, we are persuaded to use one different outcome measure to evaluate the OPO's performance in the Hawaii DSA. Instead of using the organ transplantation rate as one measure, we will use the kidney transplantation rate for only the OPO serving the Hawaii DSA. We agree with the commenters that the OPO for this DSA has a clear geographic hurdle to placing extra-renal organs. We will use the same general methodology as the organ transplantation rate for calculating the kidney transplantation rate. We will not age-adjust the kidney transplantation rates for the same reason that we do not age-adjust the donation rates. The age of 75 cutoff provides sufficient age-adjustments for kidney transplantations.

Although we are not using the organ transplant rate for the Hawaii DSA, we will continue to monitor the development and FDA clearance of organ transport devices and expect the OPO serving the Hawaii DSA to adopt these new technologies when they are available. Moreover, we will also use the same donation rate measure for the Hawaii DSA in assessing the OPO's performance since almost all donors of other organs are also kidney donors. Like all of the other OPOs, the Hawaii DSA will be evaluated based on two outcome measures.

We do not intend to give the OPO servicing Puerto Rico any special consideration for their organ transplantation rates. We made the initial decision to not provide special consideration to the Puerto Rico OPO because of its geographic proximity to parts of the continental U.S. that have significant need for organ transplants. Our analysis of 2018 data confirmed our assessment that the OPO based in Puerto Rico does not need special consideration because that OPO would be assigned as a Tier 1 OPO if the metrics where in effect at that time. We suspected that their performance in 2017 had been significantly hampered by the multiple, strong hurricanes, rather than by sustained geographic disparities that do not change from year to year. This suspicion was confirmed by the significantly higher level of performance that the Puerto Rico OPO attained in 2018 when the island was not as impacted by hurricane activity.

Final Rule Action: We are finalizing in response to comments at § 486.318(e)(7) that for the OPO exclusively serving the Hawaii DSA, the

kidney transplantation rate will be used instead of the organ transplantation rate. The comparative performance and designation to a tier will be the same as in paragraphs (e)(4), (5), and (6) except kidney transplantation rates will be used.

10. Assessment and Data for the Outcome Measures §§ 486.302 and 486.318(f)

In the December 2019 OPO proposed rule, we proposed to assess OPO performance every year, using the most recent 12 months of data from the CDC's MCOD files. Based on the typical timing of the release of the MCOD files, we expect to calculate the outcome measures near the beginning of each calendar year, and the assessment period data will have a 1-year lag. We explained that the reason we were using only 1 year of data is that we did not want to penalize OPOs who have made the effort to improve performance by using their older data in the outcome measure calculations.

Comment: Some commenters stated that 1 year of data was appropriate for the assessment period for purposes of QAPI remediation, but felt that 3 years of data should be used for re-certification. Other commenters supported our use of 1 year of data for re-certification stating that 36 months of data was too long.

Response: In the December 2019 OPO proposed rule, we stated that the reason we are using just 1 year of data is that we want to encourage and reward OPOs who make substantial efforts to improve their performance. If we use all the data from the agreement cycle in our QAPI and re-certification, the older data could mask the current performance of the OPO. It is CMS' belief that using the older data from the agreement cycle to assess OPO performance for re-certification may not accurately reflect the practices of the new OPO.

Comment: We received a comment that OPOs who takeover a DSA should not be held accountable for the performance of the former poorer performing OPO.

Response: Our assessment periods are normally from January 1 to December 31 based on the state death certificate data files that we receive. In our December 2019 OPO proposed rule at § 486.318(f)(3), we proposed that if an OPO takes over another OPO's DSA on a date later than January 1st, we will hold the OPO accountable for its performance on the outcome measures in the new area once 12 months of data are available. This paragraph recognizes that we need 12 months of data to conduct our analysis and that the new OPO needs the opportunity to be serving the area before they can make changes in response to the outcome measures. Based on the timing of the state death certificate data, it is very likely that most, if not all, of the data at the beginning of a new agreement cycle for a new OPO, will reflect the practices of the prior OPO. However, since we believe it is important that the OPO be aware of the past performance in the DSA and can use that performance as a benchmark for improvement, we will continue to do the evaluation of the assessment period for purposes of ranking and assessing the new OPO and other OPOs. The new OPO would not be required to take actions in its QAPI program in response to the outcome measure, as required at § 486.348(d), until 12 months of data are available. Since we are only using 1 year of data and outcome measures for the final assessment will include data from the middle of the re-certification cycle, the new OPO will not be judged on the performance of the prior OPO and will have had 1–2 years to improve performance in the DSA.

Comment: We received comments that use of only 1 year of data would be problematic for some OPOs servicing smaller DSAs that happened to have a ''bad year'' during the final assessment period of their agreement cycle. Because these OPOs are smaller, they have less data for analysis and their DSA could have greater variability in the number of deaths.

Response: We recognize that OPOs serving smaller DSAs are mathematically subject to greater variability in their inpatient deaths and number of donors and organ transplants. For this reason, the one-tailed confidence interval that we generate in calculating the donation and organ transplantation rates will account for the potential variability when we are using less data in the smaller OPOs.

As also discussed in section II.C of this final rule, for OPOs receiving an ECE extension, their data will continue to be part of the annual calculations of the outcome measures, and the OPOs' performance will be ranked with the other OPOs; the difference is that they will not be up for re-certification in that particular year. All requests for an ECE extension must occur within 90 days after the end of the extraordinary circumstance but no later than the last day of the final assessment period. To seek an ECE exception, the OPO needs to describe the extraordinary circumstance, the time period in which it occurred, why it was beyond the control of the OPO, and why it affected the OPO's performance in such a way that the data does not accurately capture the OPO's performance.

The intention of the ECE extension is to allow for those rare exceptions in which a natural disaster (such as a hurricane), a public health emergency or other similar catastrophe would disproportionately affect an OPO. We could also allow situations in which there are errors in the transmission of data to the CDC.

We believe that OPOs will use the option of seeking the extension judiciously because the request to extend their agreement by 1 year is not without risk. Once an OPO is up for recertification off-cycle from the other OPOs, their DSA could potentially be opened for competition at a time when other OPOs are not up for re-certification. While this would not matter for an OPO in Tier 1, a Tier 2 OPO may be more vulnerable to losing its DSA in competition with other OPOs who have more capacity and interest in competing in an off-cycle year.

Comment: We received comments that something could happen with staffing during that final year, such as a loss of a high-performing transplant coordinator, which could adversely affect outcomes during that final assessment period.

Response: Loss of key staff would not be considered an event outside of the OPOs' control and are inevitable in all organizations. Staffing, contingency planning, and other such activities are within the control of an OPO. As such, staffing changes would not constitute an extraordinary event.

Comment: We also received comments raising concerns about the data lag from CDC, with some commenters assuming that we are calculating rates using numerators and denominators from different time periods. We also received comments that the data lag would result in OPOs being re-certified based on data that is more than 2 years old.

Response: While there is a lag in the data from CDC, the numerator and denominator will be based on data from the same time period. We are adding clarifying language in our regulatory text at § 486.318(d)(3) to recognize that ''for calculating each measure, the data used is from the same time period as the data for the donor potential.'' Based on availability of the data from the CDC, the threshold rate determination and the final assessment period will use data from the middle of the agreement cycle. Therefore, OPOs would be notified of their performance on outcome measures for recertification approximately 15 months after the final assessment period just prior to the end of the

recertification cycle. Despite the lags in reporting death certificate data to the CDC, and even the lag in reporting donor and transplant information to the OPTN, the data is the best information available to empirically and transparently evaluate the OPOs' performance.

Final Rule Action: We are finalizing as proposed at § 486.318(f)(1) that an OPO's performance on the outcome measures is based on an evaluation at least every 12 months, with the most recent 12 months of data available from the OPTN and state death certificates, beginning January 1 of the first year of the agreement cycle and ending December 31, prior to the end of the agreement cycle.

We are finalizing as proposed at § 486.318(f)(3) that if an OPO takes over another OPO's DSA on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, we will evaluate the OPO's performance on the outcome measures in the new area once 12 months of data are available.

In response to the comments and to provide additional clarity, we are also adding a new definition, ''Assessment period'' at § 486.302 to be a 12-month period in which an OPO's outcome measures will be evaluated for performance. The final assessment period is the 12-month assessment period used to calculate outcome measures for re-certification. We are finalizing at § 486.318(f)(2) that the assessment period is the most recent 12 months prior to the evaluation of the outcome measures in which data is available.

We are also finalizing under § 486.318(d) a clarification for calculating each measure. All OPOs will be evaluated based on two measures. For all OPOs, the numerator for the donation rate is the number of donors in the DSA. For most OPOs, the numerator for the organ transplantation rate is the number of organs transplanted from donors in the DSA. For the OPO servicing the Hawaii DSA only, the donation rate will be the same as for all other OPOs but the kidney transplantation rate will be utilized in lieu of the organ transplantation rate. The numerator for the kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA. The numbers of donors, organs transplanted, and kidneys transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11. For calculating each measure, the data used is from the same time period as the data for the donor potential.

11. Implementation Timeline

We requested comments on this proposed change in the December 2019 OPO proposed rule to the applicability of the outcome measure requirements for the cycle beginning in 2022 and ending in 2026. The current OPO certification cycle is due to end on July 31, 2022 however, the OPO agreements for the certification period extend until January 31, 2023. This extra timeframe in the agreement affords the opportunity for any appeals or competition that may occur from any potential enforcement action for non-compliance with the CfCs, including the outcome measures. Normally, absent enforcement action on the part of CMS, the OPO agreements are renewed on August 1 or shortly thereafter to coincide with the start of the next certification period.

Comment: We received a number of comments from the general public and others that encouraged us to implement these new measures as soon as possible and to hold OPOs accountable now. We also received numerous comments from OPOs, supporting a delay of implementation of the new outcome measures to begin in 2022 and end in 2026.

Response: We appreciate the robust comments related to this topic including the desire to drive performance improvements sooner while also being responsive to providing OPOs time to adapt to the new measures and improve performance where needed. We considered the option of extending the current agreements by 2 years and assessing OPOs based on data from 2023 holding OPOs accountable to the new performance measures in 2024. However, the effects of the current COVID–19 PHE are still uncertain in regards to the impact to the organ donation and transplantation system. We note that current data from the OPTN indicate that as of November 7, 2020, there were 28,506 deceased organ transplants conducted compared to 27,658 at this same time the year prior suggesting the impacts may not be as severe as originally anticipated.[18] Therefore, we intend to implement the new measures as proposed, beginning in the 2022 recertification cycle. We believe extending implementation beyond this timeframe will negatively impact our efforts drive improvements to make these critically important life-saving organs sooner.

OPOs will continue to receive performance measures under the current metrics until the end of the current certification cycle in 2022. However, we intend to also begin providing OPOs an assessment of their performance under the new metrics in each DSA immediately using data from 2019. OPOs will receive results of their performance on the outcome measures from 2019 in the first quarter of 2021 with additional assessments being provided annually. We will rank OPO performance to provide information that may be utilized for purposes of QAPI programs interventions leading up to implementation of the new measures. OPOs will receive performance assessments in the first quarter of the year for their performance 2 years prior. As previously stated, this time lag is inherent the use of objective, reliable, and transparent publically available data sources. It affords the CDC time to collect all information and develop the report for public posting. Additionally, it provides time for CMS to receive and process information, conduct analysis, share preliminary results with OPO, and make the files public. Therefore, for the 2022–2026 certification period, the threshold rate will be established based on data from 2023 and the final assessment period will utilize data from 2024. CMS will conduct activities for recertification in early 2026, including publication of tier ranking in performance measures and conducting onsite surveys of OPO operations. While we acknowledge that OPOs will not know the actual threshold rate that will be utilized for the final assessment period until after it is complete, they will have the results of prior years from which to trend and incorporate into their QAPI program to assist in improving performance. Additionally, we expect that OPOs implement a comprehensive data-driven QAPI program to monitor and evaluate their performance. Therefore, OPOs should already be including a range of data and activities for this purpose that will inform and drive performance toward success in achieving Tier 1 status on the outcome measures and the new QAPI requirement at § 486.348(d) will be one component of that comprehensive plan.

Final Rule Action: This final rule will be effective 60 days after the publication date and the new outcome measures will be implemented on August 1, 2022 to coincide with the start of the next certification period.

12. Definitions § 486.302

In the December 2019 OPO rule, we proposed to remove several definitions from § 486.302, since these terms would no longer apply. Specifically, we proposed to remove the definitions of

[18] *https://unos.org/covid/.*

''eligible death,'' ''eligible donor,'' ''expected donation rate,'' ''observed donation rate'', and ''Standard criteria donor (SCD)''. We proposed to revise the definition of ''Donor'' described in section II.B.3 of this final rule and we will add the terms ''Assessment period'' described in section II.B.10 of this final rule, ''Death that is consistent with organ donation'' described in section II.B.6 of this final rule, ''Donation rate'' described in section II.B.2 of this final rule, ''Donor potential'' described in section II.B.6 of this final rule, ''Kidney transplantation rate'' described in section II.B.9 of this final rule, ''Lowest rate among the top 25 percent'' described in section II.B.8 of this final rule, and ''Organ transplantation rate'' described in section II.B.4 of this final rule. Public comments related to these definitions and our responses are addressed in sections II.B of this final rule as described above. The addition of ''assessment period'' and ''kidney transplantation rate'' were not proposed, and are being added in response to public comments and to provide convenience in understanding the other definitions being defined in the regulation text. The term ''Lowest rate among the top 25 percent'' was proposed, and we did not receive any comments regarding our methodology for calculating this rate. Therefore, we are finalizing with technical edits. We will define these terms as follows:

- ''*Assessment period*'' is a 12-month period in which an OPO's outcome measures will be evaluated for performance. The final assessment period is the 12-month assessment period used to calculate outcome measures for re-certification.

- ''*Death that is consistent with organ donation*'' means all deaths from the state death certificates with the primary cause of death listed as the ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–1–Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation.

- ''*Donor potential*'' is the number of inpatient deaths with in the DSA among patients 75 and younger with a primary cause of death that is consistent with organ donation. For OPOs servicing a hospital with a waiver under § 486.308(e), the donor potential of the county for that hospital will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county.

- ''*Donation rate*'' is the number of donors as a percentage of the donor potential.

- ''*Kidney transplantation rate*'' is the number of kidneys transplanted from donors in the DSA as a percentage of the donor potential.

- ''*Lowest rate among the top 25 percent*'' will be calculated by taking the number of DSAs in the time period identified for establishing the threshold rate. The total number of DSAs will be multiplied by 0.25 and rounded to the closest integer (0.5 will round to the higher integer). The donation rates and organ transplantation rates in each DSA will be separately ranked and the threshold rate will be the rate that corresponds to that integer when counting down the ranking.

- *Organ* means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ if it is used for research or islet cell transplantation.

Organ type	Number of organs transplanted
Right or Left Kidney	1
Right and Left Kidney	2
Double/En-Bloc Kidney	2
Heart	1
Intestine	1
Intestine Segment 1 or Segment 2	1
Intestine Segment 1 and Segment 2	2
Liver	1
Liver Segment 1 or Segment 2	1
Liver Segments 1 and Segment 2	2
Right or Left Lung	1
Right and Left Lung	2
Double/En-bloc Lung	2
Pancreas (transplanted whole, research, islet transplant)	1
Pancreas Segment 1 or Segment 2	1
Pancreas Segment 1 and Segment 2	2

- *Organ transplantation rate* is the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs transplanted into patients on the OPTN waiting list as part of research are included in the organ transplantation rate. The organ transplantation rate will be risk-adjusted for the average age of the donor potential using the following methodology:

(1) The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

(2) Calculate a national age-specific transplantation rate for each age group. An expected transplantation rate for each OPO is calculated as **Σ**(g=1)Gdg*Rg/**Σ**gdg, where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific national transplantation rate in age group g, and **Σ**gdg is the OPO's total number of individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

(3) Calculate the age-adjusted organ transplantation rate as (O/E)*P, where O is the OPO's observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

Comment: We received several public comments related to the deletion of definitions.

Response: We have addressed all comments related to the deletion of definitions in our discussion about the outcome measures throughout section II.B of this final rule. Comments and responses were addressed in the manner to how they applied to the related new or revised definitions. Eligible death was described in the context of the donor potential in section II.B.6; eligible donor and standard donor criteria in the context of donor definition at section II.B.3; and expected donation rate in the context of risk adjustments at section II.B.7 of this final rule.

Final Rule Action: Under § 486.302, we are finalizing as proposed, the removal of the following definitions: ''*Eligible death,*'' ''*Eligible donor,*'' ''*Expected donation rate,*'' ''*Observed donation rate,*'' and ''*Standard criteria donor* (SCD).'' We are also finalizing as proposed, by adding the definition of ''*Donation rate.*'' We are finalizing as proposed with modifications, the definitions of ''*Donor potential*'' and ''*Organ transplantation rate.*'' And we are finalizing the new definitions: ''*Assessment period,*'' ''*Death that is consistent with organ donation,*'' and ''*Kidney transplantation rate.*''

C. Re-Certification and Competition Processes (§ 486.316)

1. Re-Certification and Competition Processes § 486.316(a)

In the December 2019 OPO proposed rule, we proposed to revise § 486.316(a) to provide that the OPO must meet the performance requirements of the outcome measures at § 486.318 at the end of the re-certification cycle; and has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360.

We proposed revisions at § 486.316(a)(1) to correspond to our proposed outcome measures that were

set forth at § 486.318 in the December 2019 OPO proposed rule. To be consistent with the tier system finalized in this rule, we also need revised § 486.316(a)(1), (a)(2) and (a)(3) to reflect that the OPO has been shown by a survey to be in compliance with the conditions for coverage from ''§§ 486.320 through 486.360,'' so that it is included § 486.360 Conditions for Coverage: Emergency Preparedness, which was effective on November 15, 2016 (81 FR 63859). We are finalizing the inclusion of § 486.360 in § 486.316(a)(1)(i), (a)(2)(i) and (a)(3)(i).

In addition, we proposed to remove § 486.316(a)(3), which provided that for the 2022 recertification cycle only, an OPO is recertified for an additional 4 years and its service area is not opened for competition when the OPO meets one out of the two outcome measure requirements described in § 486.318(a)(1) and (3) for OPOs not operating exclusively in the noncontiguous States, Commonwealths, Territories, or possessions; or § 486.318(b)(1) and (3) for OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions. An OPO is not required to meet the second outcome measure described in § 486.318(a)(2) or (b)(2) for the 2022 recertification cycle. We intend to relocate paragraphs (a)(3) and (b)(2) to paragraph (g) due to the proposed new outcome measures set forth at § 486.318 becoming effect at the start of the next recertification cycle in 2022.

As described in sections II.B ''Proposed Changes to Definitions (§ 486.302)'' and ''Proposed Changes to Outcome Requirements (§ 486.318)'' of this final rule, we are not only finalizing new outcome measures, but we are also finalizing a tier system. The tier system will determine whether the OPO is immediately re-certified, must compete to retain its DSA, or will receive an initial de-certification determination. Thus, we are amending our proposal and finalizing § 486.316(a) to incorporate the tier system.

Final Rule Action: We are finalizing § 486.316(a) by incorporating the language for the tier system to indicate the requirements for each tier. We are also finalizing the inclusion of § 486.360 in the CfCs that all OPOs must meet for re-certification. We are also revising § 486.316(a)(3) as discussed above.

2. De-Certification and Competition Processes § 486.316(b)

In the December 2019 OPO proposed rule, we proposed that if an OPO does not meet the performance requirements or the outcome measures as described in paragraph (b) of this section at the final assessment prior to the end of the re-certification cycle or the requirements described in paragraph (b)(2) of this section, the OPO would be de-certified. If the OPO does not appeal, or the OPO appeals and the reconsideration official and CMS hearing officer uphold the decertification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

As discussed in section II.B of this final rule and based on the comments we received, we are finalizing new outcome measures, for all OPOs, and except for the Hawaii DSA, those measures are the donation and the organ transplantation rates. Based on public comments, we are also establishing a tier system that will be used to classify OPOs for purposes of re-certification, decertification, appeals, and competition. The outcome measures and tier system are discussed in detail in sections II.B.2, II.B.4, and II.B. 6 through 10 of this final rule.

We requested comments on competition, including whether all DSAs should be opened at the end of the re-certification cycle for competition under § 486.316. Only one of the commenters wanted all of the DSAs open for competition each re-certification cycle regardless of the OPO's performance. Most of the commenters, however, wanted more competition than existed under our prior rules and contended that more competition would improve OPO performance. Some commenters suggested that OPOs that were doing well should not have to compete to retain their DSAs because it would divert resources from their primary mission of procuring organs. This finalized rule does provide for more competition to drive improvements in performance. Prior to this finalized rule, OPOs were either re-certified or de-certified based on their outcome measures. In this final rule, OPOs will be assigned to a tier based on their outcome measures. Only those OPOs that are designated as Tier 1 OPOs will not have their DSAs opened for competition (§ 486.316(a)). Tier 3 OPOs will be decertified and, following any appeals, their DSAs will be opened for competition, unless the de-certification is reversed as a result of the appeals process. With respect to Tier 2 OPOs, those DSAs will also be opened for competition. The incumbent OPO will have to compete if the OPO wants to retain its DSA and the DSA will also be open for competition from any other OPO that is qualified to compete for open DSAs. If a Tier 2 OPO does not win the competition for its DSA and does not win the competition for any other open DSA it competes for, CMS will not renew its agreement with the OPO. The OPO will not be able to appeal this non-renewal, which is not a de-certification. The change to a tiered approach increases the number of DSAs open for competition and the number of OPOs eligible to compete for open DSAs, which is consistent with the recommendation of most public commenters. Although we proposed to change the criteria for competition at § 486.316(c) to correspond to the new outcome measures in § 486.318, we did not propose any changes to the selection criteria for competition at § 486.316(d). We appreciate all of the commenters that submitted comments on the competition process. Those comments have been reviewed and will be considered in any future rulemaking

Comment: Some commenters contended that de-certification was too severe of a consequence for OPOs below the lowest rate among the top 25 percent. Those commenters do not believe that this would provide incentive for OPOs to improve their performance.

Response: The establishment of the tier system should provide OPOs with the incentive to improve their performance. We believe that it is realistic that all OPOs, even those that we have estimated would be de-certified based on their past performance, can avoid de-certification by improving their performance. After considering public comments, we have lowered the level of performance that would lead to an OPO being decertified. We do not agree with the commenter that de-certification is too severe of a consequence for Tier 3 OPOs. If an OPO cannot achieve the outcome measures we are finalizing in this rule, or cannot demonstrate compliance with the OPO CfCs through its re-certification survey, we believe that de-certification is the appropriate consequence.

In reviewing our proposal in light of this comment, however, we believe that the language in this section should be clarified. In the December 2019 OPO proposed rule, we said, ''the OPO is de-certified.'' We believe that statement could be misleading. As set forth in § 486.314(a), when CMS determines that an OPO will be de-certified because of involuntary termination or non-renewal of its agreement with CMS, CMS will

mail the OPO an initial de-certification determination. The OPO then has the appeal rights set forth in § 486.314. Thus, we are revising the language from what we proposed at § 486.316(b) by removing, ''the OPO is de-certified'' and inserting ''CMS will send the OPO a notice of its initial de-certification determination and the OPO has the right to appeal as established in § 486.314''. We have also separated the three requirements after the stem statement to improve clarity and readability.

Comment: Some commenters contended that the OPO CfCs did not need the drastic changes we proposed. Some commenters contended that many OPOs were performing well and the system was not underperforming to the extent that the proposed rule contended.

Response: We agree that some OPOs, as demonstrated by their performance on our assessment of their performances based the new outcome measures, are doing a great job in procuring transplantable organs and working with donor families. This is why we are finalizing the tier system that recognizes those OPO's superior performance. In addition, the estimated number of OPOs that would be de-certified under the proposed rule (refer to Table 3 in the 2019 December OPO proposed rule) was based on the past performance of the OPOs. We believe that OPOs will be incentivized to improve their performance because of the outcome measures and tier system finalized in this rule. At the end of the first re-certification that uses these outcome measures and tier system, we believe that fewer OPOs will be de-certified.

Comment: One commenter was concerned about unintended consequences of the requirements that may come to light if the proposals were finalized.

Response: In any change of regulation, there is always a possibility of unintended consequences. We have taken all of the appropriate steps necessary to consider and develop outcome measures that we believe will improve OPO performance and increase the number of transplantable organs for those individuals on the waiting lists. In addition, OPO performance and patient access impacts will be monitored closely. If any unintended consequences come to our attention, we will appropriately evaluate and address them at that time.

Comment: Some commenters expressed concern that increased pressure from the new outcome measures and the threat of de-certification would damage the relationships between the OPOs so that they will no longer cooperate or share best practices with each other. The commenter noted that this was especially concerning since the OPTN is moving towards a geographical allocation system, which makes cooperation between OPOs even more important. One commenter contended that the proposal had already damaged some collaboration between OPOs.

Response: While collaboration between OPOs is a worthy goal, such collaboration has not resolved the significant, ongoing disparities that exist in OPO outcomes. Thus, it is CMS' belief that it is necessary to revise the current policies. We believe that the need for additional organs presents such a great need as to outweigh any impacts to OPO collaboration. Thus, in order to achieve such a benefit, it is necessary for incentives for OPOs to improve performance or face competition and decertification.

By finalizing a tiered system, only OPOs that are not in compliance with the outcome measures, or found to be not in compliance with the conditions for coverage at the re-certification survey, will be designated as Tier 3 and receive a notice of de-certification. Many OPOs that would have been de-certified under the proposed outcome measures will be designated in Tier 2 and have the opportunity to compete to retain their DSAs. While this approach may change the nature of recertification, we do not believe it should change the nature of OPO relationships with each other. Cooperation among other OPOs in procuring and placing organs could not only improve an OPO's performance on the outcome measures, but also increase the number of transplantable organs.

Based upon this tiered system, OPOs that fail to meet the outcome measures as specified in § 486.318(e)(6), that is an OPO that fails to meet the median threshold for the donation or transplantation measures, fails to meet the median threshold for the donation and transplantation measures or fails to demonstrate compliance with the OPO CfCs via the re-certification survey, will be the only OPOs that are designated into Tier 3. An OPO that qualifies for Tier 3 designation will receive an initial notice of de-certification determination, has the appeal rights set forth at § 486.314, and, if decertified, cannot compete for either its own or any other open DSA.

Final Rule Action: We are modifying § 486.316(b) to correspond to the tier system we are finalizing for OPOs. In addition, to clarify the requirements associated with this modification, we have also designated three requirements at paragraphs (b)(1) through (b)(3). Paragraph (b)(1) to clarify that the OPO will receive a notice of initial de-certification determination and the OPO has the right to appeal as established in § 486.314. Paragraph (b)(2) clarifies that the DSA will be open for competition and the OPO cannot compete for its DSA or any other DSA that is open for competition. Paragraph (b)(3) clarifies that the OPO must continue to perform its functions in the DSA until a successor OPO is selected and there has been an orderly transition to the new OPO.

3. Criteria To Compete § 486.316(c)

The current requirements set forth at § 486.316(c) state that for an OPO to compete for an open DSA, it must meet the criteria for re-certification and meeting the following criteria: (1) The OPO's performance on the donation rate outcome measure and yield outcome measure is at or above 100 percent of the mean national rate averaged over the 4 years of the re-certification cycle; (2) The OPO's donation rate is at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area; and (3) The OPO must compete for the entire service area. We proposed to modify this section by requiring the OPO to meet the performance measures set forth in § 486.318 and the requirements for certification at § 486.303, including the CfCs at §§ 486.320 through 486.360. We also proposed to retain the requirements that the OPO would have to compete for the entire DSA. Except for the last requirement, these proposed changes were necessary to correspond to the proposed outcome measures. We proposed to remove ''§ 486.348'' and insert ''§ 486.360'' so that it included § 486.360 Conditions for Coverage: Emergency Preparedness, which was effective on November 15, 2016 (81 FR 63859). This change will be incorporated into § 486.316(a) and § 486.316(c).

Comment: Commenters generally supported the proposed changes, except for the requirement for the competing OPO(s) to compete for the entire open DSA. At least one commenter recommended that there would be more competition if an OPO could compete for a portion, rather than the entire, open DSA.

Response: We respectfully disagree. Since the 2006 OPO final rule, we have required that any OPO that is competing for an open DSA must compete for the entire DSA. OPOs do not have the discretion to decide whether a DSA's boundaries should be adjusted. CMS can adjust or change the boundaries for a DSA consistent with statutory criteria. Moreover, we believe it would be

detrimental to patients and to the system if particular segments were carved out. Under the final rule, all of the OPOs that choose to compete would be competing for the same geographic territory.

Final Rule Action: We are finalizing § 486.316 (c) as proposed, with changes to address the tier system. Specifically, we are adding a reference to ''Tier 1 or Tier 2 at § 486.318(e)(4) and (5) instead of the broader reference to § 486.318 as we proposed.

4. Criteria for Selection § 486.316(d)

Section 486.316(d) originally stated that, ''CMS will designate an OPO for an open service area based on the following criteria.'' In the December 2019 OPO proposed rule, we proposed to modify the stem statement to read, ''CMS will consider the following criteria in designating an OPO for an open DSA.'' Our original intention was for the criteria listed in this section to be guidelines instead of a strict criteria for selection.

We did not, however, solicit comments on all aspects of § 486.316(d), including the requirements that would be used for competition (84 FR 70635) on selection criteria. We did receive some comments for this requirement. However, we did not solicit comments in a manner that would allow us to receive comments and consider a full range of factors that may impact selections. Those comments have been reviewed and will be considered for future rulemaking.

Final Rule Action: We are finalizing § 486.316(d) as proposed.

5. Extension of the Agreement Cycle for Extraordinary Circumstances § 486.316(f)

We did not propose any exception to the outcome measures requirement if the OPO experienced a disaster or some sort of extraordinary circumstance that was beyond its control and negatively impacted the OPO's performance during the final assessment period of the re-certification cycle.

Comment: We received comments that there may be natural disasters or events beyond the OPOs control that could happen during that final assessment period.

Response: As discussed above, we recognize that there may be circumstances beyond the OPO's control that could adversely affect the data in the final assessment period of the agreement cycle. The consequences of these events for the QAPI revision is less significant because re-assessment of performance and making changes to improve performance is a continuous process. For re-certification, a natural disaster (such as a hurricane) or an infectious disease outbreak (such as an epidemic) that could impact DSAs disproportionately or have a disparate impact between the OPOs. Pursuant to these comments, we are revising the regulations at § 486.316(f), as described in more detail below, to include an extension of the agreement cycle for extraordinary circumstances.

These comments demonstrate that there could be extraordinary circumstances that are beyond an OPO's control that could negatively impact the OPO's performance on its outcome measures. This could result in an OPO's performance not being accurately captured by the outcome measures. It is our intention to set empirical and transparent metrics for performance, and understand that there are extraordinary circumstances that could compromise or skew the underlying data. These extraordinary circumstances could include problems with the data such as data submission or transfer, a natural disaster, or other events with disparate effects. Therefore, we are finalizing that an OPO may apply for an extension of its agreement with CMS for 1-year. This is only for the final assessment period of the re-certification cycle when there has been and extraordinary circumstance beyond the OPO's control. The OPO must request this extension within 90 days of the end of the occurrence but no later than the last day of the final assessment period.

Final Rule Action: We are finalizing § 486.316(f) that provides for OPOs to seek a 1-year extension of the agreement cycle if there are extraordinary circumstances beyond the control of the OPOs that has affected the data of the final assessment period so that it does not accurately capture their performance. OPOs must request this extension within 90 days of the end of the occurrence of the extraordinary circumstance but no later than that last day of the final assessment period.

D. Reporting of Data § 486.328

In the December 2019 OPO proposed rule, we proposed to eliminate the reporting of the ''Number of eligible deaths'' and modifying the reporting of the ''Number of eligible donors'' to ''Number of donors'' to correlate with the changes of our outcome measures. We also proposed to revise language in this section that incorrectly refers to the ''Scientific Registry of Transplant Beneficiaries'' and ''DHHS.'' We did not receive any comments that we should continue to collect eligible death information if it is not being used, nor did we receive comments about the correction in the other language.

Final Rule Action: We are finalizing at § 486.328(a) by removing the word ''Beneficiaries'' and adding in its place the word ''Recipients'' and by removing the acronym ''DHHS'' and adding in its place the acronym ''HHS.'' We are finalizing at § 486.328(a)(4) by removing and reserving the reporting of the ''Number of eligible deaths,'' and revising at § 486.328(a)(7) by removing the word ''eligible and revising the language to say ''Number of donors.'' We are also removing and reserving paragraph (a)(4) of § 486.328.

E. Proposed Change to the Quality Assessment and Performance Improvement Requirement (§ 486.348)

In the December 2019 OPO proposed rule, we proposed at § 486.348(d) to require that OPOs include a process to evaluate and address their outcome measures in their QAPI program if their rates are statistically significantly lower than the top 25 percent at each assessment, for each assessment period except the final assessment. Failure to meet the outcome measure in the final assessment period would result in de-certification. For all other assessment periods, if the OPO does not meet the outcome measures, the OPO must identify opportunities for improvement and implement changes that lead to improvement in these measures.

As we stated in the December 2019 OPO proposed rule (84 FR 70628), an OPO that was deemed compliant on its QAPI, but did not meet one or both of the proposed outcome measures that would be subject to decertification. We also sought comments as to whether § 486.348(b) should be revised or removed altogether to eliminate death record reviews since we are no longer using eligible deaths.

Comment: Most commenters supported the concept that ongoing performance improvement should be a goal of the organ procurement and transplantation community. However, commenters suggested that we include a process for performance improvement for OPOs which don't initially meet the metrics before proceeding with decertification. These commenters stated that a systematic approach to decertification provides structure and guidance to lower performing organizations and allows for guidance to improve. They also stated that this improvement will create more stability in the nationwide system and ultimately lead to the end goal of improving performance without disrupting the network of service providers. Commenters stated that using the most

recent 12 months of data gives a more accurate view of the OPOs performance, using the entire 4 years is too long. On the other hand, some commenter's stated that every 12 months is too often and should be only required at least once during the 4-year cycle.

Response: We believe that all OPOs have the potential to improve. Thus, we are finalizing that every 12 months during the 4-year cycle, an OPO will be assessed for its performance on the outcome measures. During that assessment, if the OPO is performing lower than the 25 percent threshold rate, they will have the opportunity to develop a performance improvement plan to improve performance through their QAPI program. The use of annual review allows the OPO to more swiftly identify and address potential problems. We proposed to require that OPOs include a process to evaluate and address their QAPI program if their rates are statistically significantly lower than the top 25 percent at each assessment, for each assessment period, except for the final year. However, public comment supported completing QAPI in all 4 years of the certification period, so we have decided to include the final year in the assessment to allow the OPO to identify opportunities for improvement and implement the changes to improve performance.

Comment: One commenter suggested that the donor hospital CoPs should track organ donation and work to improve the donation process and that this information from donor hospitals should be tracked by CMS. By collecting and reviewing this data from donor hospitals, CMS would be able to use this data to identify ''best practices'' to share with the donation community. The commenter suggested CMS consider establishing a method to measure and ensure that all three entities (donor hospitals, OPOs, and transplant hospitals) are fulfilling the expectations outlined in federal regulations.

Response: The actions of donor hospitals and their data submission are outside of the scope of this rule. We will consider this suggestion for future rulemaking related to the hospital Conditions of Participation.

Comment: A few commenters questioned whether or not the OPOs are receiving all the information, resources and expertise that they need to be successful in their outcome measures and QAPI programs.

Response: There are many organizations that are available to help OPOs perform the best job possible for organ donors and recipients. The OPTN, through its contract with UNOS, is an organization that provides tools, resources, and expertise to help OPOs improve the quality of service they provide, in order to achieve our joint goal of placing donated organs equitably and efficiently and saving more lives. This process involves continuously evaluating new advances and discoveries so policies can be adapted to best serve patients waiting for transplants. All transplant programs and organ procurement organizations throughout the country are OPTN members. We have heard from commenters and seen changes since the publication of the December 2019 OPO proposed rule, such that we are confident that through collaboration and the sharing of best practices, the industry is capable of ongoing performance improvement.

Final Rule Action: After consideration of the public comments, we are finalizing our proposal at § 486.348(d) with modification. We will include the review of the QAPI program for all 4 years of the recertification cycle.

1. Death Record Review in QAPI

In the December 2019 OPO proposed rule, we requested comments as to whether the requirement related to monthly death record reviews at § 486.348(b) should be revised or removed altogether.

Comment: We received mixed comments on whether we should eliminate the death record review as part of the QAPI at § 486.348(b). Those who wanted to remove the requirements commented that death record reviews were a tremendous amount of work. Those who suggested that we should retain the requirement found value with the death record reviews.

Response: We are not revising § 486.348(b) to remove the requirement for the death record review. While we appreciate comments related to potential burden from these reviews, commenters also reported important added value from the information. The reviews support verifying accuracy of data reported to the OPTN by the OPO, identify potential missed opportunities for donation, facilitate collaboration with donor hospitals through sharing of results, and facilitate internal QAPI activities. Additionally, data from death record reviews may provide relevant information for judging OPO performance during the survey process.

Final Rule Action: We will not revise § 486.348(b) to remove the requirement for the death record review.

F. Solicitation of Comments

We received many responses to our solicitation of comments in the December 2019 OPO proposed rule. The comments we received have been addressed in sections II.A, II.B, II.C of this final rule regarding outcome measures, general comments, competition process and recertification.

1. Out of Scope

Comment: We received several comments pertaining to issues that are outside the scope of the proposed rule. Those comments concerned transplant program outcome measures/harmonizing outcome measures, comments about Medicare and Medicaid spending and FDA approval of drugs relating to organ transplants. In addition, some commenters sought to change instructions to donor hospitals through hospital CoPs, transplant program CoPs, and OPO governance issues.

Response: We thank the commenters for their feedback. However, these issues are outside the scope of the final rule that focused primarily on the outcomes measures for OPOs and the consequences of recertification or decertification of OPOs because of the changes such measures. We will review these comments and consider for potential future rulemaking.

III. Provisions of the Final Rule

In this final rule, we are adopting the provisions of the December 2019 OPO proposed rule (84 FR 70628) with the following revisions:

A. Proposed Changes to Definitions (§ 486.302) and Proposed Changes to Outcome Requirements (§ 486.318).

- We are finalizing as proposed with modifications, the definitions of ''*Donor potential*'' and ''*Organ transplantation rate.*'' And we are finalizing the new definitions: ''*Assessment period*'' and ''*Death that is consistent with organ donation,*'' and ''*Kidney transplantation rate.*
- We are finalizing our proposal at § 486.318(d)(4) in this final rule using the death certificate data to calculate the donor potential.
- We are finalizing a modification to the definition of the ''donor potential'' under § 486.302 to apportion the donor potential in a county where there is a donor hospital that has sought a waiver to work with an OPO out of their designation service area. For OPOs servicing a hospital with a waiver under § 486.308(e), the donor potential of the county for that hospital will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county.

• We are finalizing under § 486.302 that ''death that is consistent with organ donation'' means all deaths from state death certificates with the primary cause of death listed as the ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–1–Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation.

• We are finalizing the new definition, ''Assessment period'' under § 486.302 to be a 12-month period in which an OPO's outcome measures will be evaluated for performance. The final assessment period is the 12-month assessment period used to calculate outcome measures for re-certification.

• We are finalizing that the kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA as a percentage of the donor potential.

• We are finalizing as proposed that the age cutoff for the donor potential defined in § 486.302 is 75 and younger.

• We are finalizing the definition of ''organ transplantation rate'' under § 486.302 to be risk-adjusted for the average age of the donor potential using the following methodology:

(1) The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

(2) Calculate a national age-specific transplantation rate for each age group. An expected transplantation rate for each OPO is calculated as **Σ**(g=1)Gdg*Rg/**Σ**gdg, where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific national transplantation rate in age group g, and **Σ**gdg is the OPO's total number of individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

(3) Calculate the age-adjusted organ transplantation rate as (O/E)*P, where O is the OPO's observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

• We will be finalizing the implementation this final rule 60 days after publication and the new outcome measures will be implemented on August 1, 2022 to coincide with the start of the next certification period.

• We are finalizing our proposal at § 486.318(d)(1) that the donation rate will be one of the outcome measures for assessing OPO performance, and is defined as the number of donors as a percentage of the donor potential.

• We are finalizing our proposal at § 486.318(d)(2) that the organ transplantation rate will be an outcome measure for assessing OPO performance, and is defined as the number of organs transplanted from donors in the DSA as a percentage of the donor potential.

• We are also finalizing under § 486.318(d)(3) a clarification that for calculating each measure. The numerator for the donation rate is the number of donors in the DSA. The numerator for the organ transplantation rate is the number of organs transplanted from donors in the DSA. The numerator for the kidney transplantation rate is the number of kidneys transplanted from donors in the DSA. The numbers of donors, organs transplanted, and kidneys transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11. For calculating each measure, the data used would be from the same time period as the data for the donor potential.

• We are finalizing our proposal that we will use the most recent 1 year of data for calculating the outcome measures for each assessment period under § 486.318.

• We are finalizing § 486.318(e)(4) through (6), the creation of three tiers to identify OPO performance.

Tier 1—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the top 25 percent threshold rate established for their DSA will be identified at each assessment period.

Tier 2—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the median threshold rate established for their DSA but is not in Tier 1 as described in paragraph (e)(4) will be identified at each assessment period.

Tier 3—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation or organ transplantation rates that are below the median threshold rate established for their DSA will be identified at each assessment period. OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are below the median threshold rate for their DSA are also included in Tier 3.

• We are finalizing under § 486.318(e)(7) that for the OPO exclusively serving the DSA that includes the non-contiguous state of Hawaii and surrounding territories, the kidney transplantation rate will be used instead of the organ transplantation rate. The comparative performance and designation to a Tier will be the same as in paragraphs (e)(4), (5), and (6) except kidney transplantation rates will be used.

B. Re-Certification and Competition Processes (§ 486.316)

• We are modifying our proposed changes to § 486.316(a), (b), and (c) to make corresponding changes for the tier system we are finalizing.

• We are modifying the language in § 486.316(b) by removing ''the OPO is de-certified'' and inserting ''CMS will send the OPO a notice of its initial de-certification determination and the OPO has the right to appeal as established in § 486.314''.

• We are finalizing under § 486.316(f) that OPOs can seek a 1-year extension of the agreement cycle if there are extraordinary circumstances beyond the control of the OPO that has affected the data of the final assessment so that it does not accurately capture their performance. OPOs must request this extension within 90 days of the end of the occurrence of the extraordinary circumstance but no later than that last day of the final assessment period.

C. Proposed Change to the Quality Assessment and Performance Improvement Requirement (§ 486.348)

• We are finalizing our proposal at § 486.348 with modification. We will include the review of the QAPI program for all 4 years of the re-certification cycle.

• We are not revising § 486.348(b) to remove the requirement for the death record review.

D. Solicitation of Comments (Including Changes to Re-Certification Cycle)

We solicited comments in the December 2019 OPO proposed rule on the following issues:

• Should OPO outcome measures also include an assessment of organ transplantation rates by type of organ transplanted?

• We are proposing to use a performance measure that is based on the OPO's performance relative to the top 25 percent of donation rates and organ transplantation rates. Should CMS use a static level or a different criterion from what is being proposed? What statistical approach to the data or incentives can we use to encourage all OPOs to strive to be high performers? Can the current performance parameter, which requires that the donation rate be no more than 1.5 standard deviations

below the mean national donation rate, be appropriately applied to achieve this goal? We are requesting that commenters explain and include any evidence or data they have to support their comments.

• What are the benefits, consequences, or unintended consequences, of using these two proposed measures and what are their potential impact on OPOs, transplant programs, organ donation, patient access, and transplant recipients?

• Are there potential additional compliance burdens on OPOs or transplant programs if the two proposed measures were finalized?

We received robust public comments in response to this solicitation that have been summarized and responded to as part of the discussions in sections II.A through C of this final rule.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We received no comments on the need for information collection, the accuracy of our estimates, the quality or utility of the information to be collected, or the information collection burden estimates.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Extension of Agreement Cycle for Extraordinary Circumstances (§ 486.316)

In this final rule at § 486.316(f), we have added a paragraph in response to public comments allowing for an extension of the agreement cycle for extraordinary circumstances. OPOs may seek a 1-year extension of the agreement cycle if there are extraordinary circumstances beyond the control of the OPOs that has affected the data of the final assessment period so that it does not accurately capture their performance. OPOs must request this extension within 90 days of the end of the occurrence of the extraordinary circumstance but no later than the last day of the final assessment period. In section II.C.5 of this final rule, we state that to seek an ECE exception, the OPO needs to describe the extraordinary circumstance, the time period is which it occurred, why it was beyond the control of the OPO, and why it affected their performance in such a way that the data does not accurately capture.

We will need to submit a revised information collection request for the OPO CfC (OMB Control Number 0938–0688, expiring February 2021) information to reflect the opportunity we are providing for OPOs to request an ECE. Since requesting an ECE will place the DSA off-cycle from the other DSAs for re-certification, we expect that OPOs will be judicious in deciding to request the 1-year ECE. It is difficult to predict extraordinary events, however for the purposes of our burden estimate, we anticipate four OPOs requesting an ECE with each 4-year re-certification cycle, resulting in an average of 1 request per year.

We estimate that the OPO director ($107/hour), and a medical secretary ($35/hour) will need 1 hour each to collect relevant evidence to support the extraordinary circumstance, describe it in writing, and submit the information to CMS. All wages are adjusted upwards by 100 percent to account for the cost of fringe benefits and overhead. The result would be an annual cost of $284 (2 hours × $142).[19]

B. ICRs Regarding Re-Certification and Competition Processes (§ 486.316)

At § 486.316(b), we proposed to modify language that refers to the current outcome measure requirements that states that an OPO must meet two out of the three outcome measures at § 486.318. They would instead be required to meet both newly proposed outcome measures, or face de-certification which may then be appealed by the OPO. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area would be opened for competition by other OPOs.

In the final rule, we maintain these requirements with some modifications. Most notably, we are creating a three-tier, rather than two-tier, performance system, with OPOs performing below the threshold rate established by the top 25 percent required to update their QAPI program at each assessment period and those OPOs who are in Tier 2 (has at least the donation rate and the organ transplantation rate at or above the median threshold rate) being allowed to compete to retain their DSA rather than automatically being decertified. These changes do not significantly affect the information to be collected or the net effect of the rule on information collection, since all DSAs with outcome measures below the threshold rate of the top 25 percent would remain subject to competition.

The current information collection request for the OPO CfC (OMB Control Number 0938–0688, expiring February 28, 2021) estimates that one OPO would face de-certification per year, but under both the proposed and final rule, revised outcome measures, this number could potentially significantly increase after the first cycle of implementation. The intention for subsequent cycles is that the outcome measures of all DSAs would cluster at the top 25 percent threshold rate. We do not know exactly how many would be de-certified under these new measures. Based on the improvement required to meet the proposed rule measures, we estimated that it would be possible that approximately 7 to 33 OPOs could be de-certified. Given the change in the final rule to the three tier system and the potential for Tier 2 OPOs to retain their certification, we believe that the number would be lower. The range of decertified OPOs would thus vary from zero OPOs that are decertified, to all Tier 3 OPOs being decertified and all Tier 2 OPO DSAs being open for competition. Since there are 22 OPOs in the lowest tier, and all of these will presumably be trying to improve their performance using the assessment period data provided each year and their QAPI, it seems likely that at most about half of the OPOs (11) would be decertified based on their outcome measures in 2024. There would also be 12 OPOs in Tier 2 whose respective service areas would be opened for competition. If the 12 OPOs in Tier 2 were joined by the 22 OPOs in Tier 3, there would be 34 open DSAs subject to potential competition. Of course, with improved performance in response to the annual assessments, the number at

[19] These and subsequent estimated wage costs are based on the Labor Department's Bureau of Labor Statistics annual occupational wage survey at *https://www.bls.gov/oes/current/oes_nat.htm*. We double the hourly wage estimate to account for the costs of overhead and fringe benefits.

risk could be as low as zero. However, to be conservative we have chosen mid-point estimates to calculate estimated burden and potential impact.

Under § 486.316(d), Criteria for selection, we identify the factors that we will consider in awarding a DSA to an OPO competing for an open service area. In addition to factors that CMS will produce and collect from other aspects of the CfCs, OPO will need to submit information and data that describes the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results. In addition, § 486.316(c) states that to compete for an open service area, an OPO must meet the performance requirements of the outcome measures at § 486.318 and the requirements for certification at § 486.303, including the CfCs at §§ 486.320 through 486.360. The OPO must also compete for the entire service area.

Since much of the information about the outcome measures is already calculated and collected by CMS and performance in the CfCs at §§ 486.320 through 486.360 through the re-certification survey, the burden associated with this requirement is the time it would take to create a document that contains the required information and data related to the OPO's success in identifying and addressing the barriers in its own service area and how they relate to the open service area. We refer to this documentation as an application.

While we have never de-certified an OPO under the current rules, we know from our past experience trying to de-certify an OPO that approximately 10 other OPOs were interested in taking over the open DSA. For purposes of estimation, we assume that about half of the DSAs opened for competition based on 2018 calculations would have improved sufficiently that they would not be opened for competition in 2024: 11 DSAs with Tier 3 designation and 6 DSAs with Tier 2 designation. Since this final rule would expand the number of open DSAs, OPOs are likely to be more strategic in trying to take over an open DSA with more effort being placed to try to take over a DSA being de-certified instead of a DSA designated as Tier 2. For the Tier 3 DSAs, we assume that approximately 5 OPOs will apply for each open DSA, resulting in 55 applications. For the 6 open Tier 2 DSAs, we assume that all incumbent OPOs will try to retain their DSA and an average of 2 other OPOs will try to take over the Tier 2 DSA, resulting in 18 more applications. In total, we estimate approximately 73 applications will be developed to compete for an open DSA at each re-certification cycle. We will revise these burden estimates after the first re-certification cycle for accuracy.

We believe that developing each application would require the collective efforts of a QAPI director (Registered Nurse, $71/hour), organ procurement coordinator (RN or social worker, $71/hour), medical director ($107/hour), OPO director ($107/hour), and a medical secretary ($35/hour). All wages are adjusted upwards by 100 percent to account for the cost of fringe benefits and overhead. Assuming, consistent with past rulemaking, that it would take these professionals 104 hours to develop such an application, we estimate that a total of 7,592 hours (73 applications × 104 hours) to complete the competition for each re-certification cycle. We further estimate that 47 OPOs are eligible to compete for an open DSA and that all 12 of those OPOs (in Tier 2) will compete to retain their DSA and 4 OPOs (the top third) in Tier 2 will compete for another DSA. Of the remaining 23 OPOs who are in Tier 1, we estimate that at most (20) will try to compete for an open DSA.

We estimate that on average, each competition would require 7,592 burden hours for all 43 OPOs to complete 73 applications and would cost all 43 OPOs $644,152 (($71 RN × 30 hours × 73 applications) + ($71 organ procurement coordinator x 30 hours × 73 applications) + ($107 medical director × 12 hours × 73 applications) + ($107 OPO director × 30 × 73 applications) + ($35 medical secretary × 2 hours × 73 applications)). For the annual burden, each of these figures needs to be divided by 4, since competition for open service areas will typically occur every 4 years. Thus, the annual burden hours for all 43 OPOs to prepare 73 plans would be 1,898 (7,592/4) and the annual cost estimate would be $161,038 ($644,152/4).

C. ICRs Regarding Condition: Reporting of Data (§ 486.328)

We proposed to revise § 486.318 to eliminate the reporting of the ''Number of eligible deaths'' and modify the reporting of ''Number of eligible donors'' to ''Number of donors.'' Although the current outcome measures include the potentially burdensome OPO self-defined and self-reported ''eligible deaths'' for evaluation purposes, the current information collection request for the OPO requirements (OMB Control Number 0938–0688, expiring February 28, 2021) does not attribute any burden to this requirement. This is because the type of data and how it is reported to the OPTN is already covered by the information collection requirements associated with the OPTN final rule (§ 121). The OMB control number for this collection is 0915–0157 (expiring August 31, 2023). Thus, we are not attributing any quantifiable burden reduction to eliminating this requirement in the final rule.

D. ICRs Regarding Quality Assessment and Performance Improvement (§ 486.348)

At § 486.348(d) we are requiring that OPOs include a process to evaluate and address their outcome measures in their QAPI program if their rates are statistically significantly lower than the top 25 percent at each assessment. Assessments would occur at least every 12 months with the most recent prior 12 months of available data, meaning there would be 4 assessments in each 4-year re-certification cycle that might require modifications to these OPOs' QAPI programs.

As stated in the information collection request for the OPO requirements (OMB Control Number 0938–0688, expiring February 28, 2021), we believe the information collection requirements associated with maintaining a QAPI program are exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with this collection of information would be incurred by persons in the normal course of their activities. Accordingly, we do not believe this change would impose any additional ongoing quantifiable burden.

V. Regulatory Impact Analysis

A. Statement of Need

All major government regulations should undergo periodic review to ensure that they do not unduly burden regulated entities or the American people, and that they accomplish their goals effectively and efficiently. It has been apparent for a number of years that the current system for organ donation and the rules under which OPO performance is measured do not create the necessary incentives to optimize organ donation and transplantation as evidenced by performance discrepancies among OPOs, the wide geographic and population diversity among both higher- and lower-performing OPOs, and the significant gap between the number of potential organ donors and the number of actual donors (see Tables 1 and 2). As discussed in the December 2019 OPO proposed rule, many anecdotal article titles identify a clear need for action: ''Reforms to Organ Donation System Would Save Thousands of Lives,

Millions of Taxpayer Dollars Annually,'' ''Lives Lost, Organs Wasted,'' and ''A Simple Bureaucratic Organ Donation Fix Will Save Thousands of Lives.'' [20] All three of these articles include, or reference, in-depth studies of the current organ donation system's problems and discuss reforms that could increase its performance. These articles were written by and published in: Goran Klintman, RealClearHealth, March 4, 2019; Kimberly Kindy, Lenny Bernstein, and Dan Keating, Washington Post, December 20, 2018; and Laura and John Arnold, STAT, July 24, 2019. These problems and the reforms needed to improve organ donation and transplantation have multiple dimensions, including the underperformance of many OPOs to procure and place organs at the levels of the best-performing OPOs. This is the basis for President Trump's July 10, 2019 Executive Order on Advancing American Kidney Health, to ''increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.''

The majority of the public comments agreed that these were major problems and that many lives could be saved if reforms were made. For example, one OPO which had just greatly increased its donor performance stated that ''we know that there are many more potential donors in our DSA [and] it is our intent to act on that belief . . . Substantial, not incremental, change is required in our system.''

Relatedly, the Secretary issued a final rule on September 30, 2019, titled ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732), referred to as the ''2019 Burden Reduction final rule'', to reduce regulatory burden on several types of health care providers'') that directly addressed the same policy concern. Under that final rule, performance standards for transplant hospitals were revised to reduce the practice of transplanting only the best organs in the healthiest patients. Those performance standards rewarded high 1-year organ and patient survival rates by threatening program closure to hospitals that did not achieve such rates. In so doing, those performance standards gave no weight to maximizing treating the many patients on the waiting lists whose lives would be saved, even at a higher risk of failure. As discussed in the RIA for 2019 Burden Reduction final rule, lessening or eliminating those standards might reduce the number of ''transplant quality'' discarded organs, and through transplantation of those organs, save the lives of many patients each year. Because transplant programs had been notified over a year ago that these penalties were likely to be eliminated, the regulatory changes may have led to changes beginning in late 2018 and continuing in 2019 to utilize more organs than in previous years.

Finally, the Executive Order directs the Secretary of HHS as follows: ''Within 90 days of the date of this order, the Secretary shall propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO's performance.'' That directive applied directly to the proposed rule that preceded this final rule.

B. Scope of Review

We have examined the impacts of both the proposed rule and this final rule as required by E.O. 12866 on Regulatory Planning and Review (September 30, 1993), E.O. 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Order 13771 states that it is essential to manage the costs associated with the government imposition of private expenditures required to comply with federal regulations and establishes policies and procedures to reduce the costs of both new and existing federal regulations.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated and OMB has determined that this rule is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that presented our estimates of the costs and benefits of this rulemaking.

Based on the public comments we received, our review of these comments, our review of new research literature, and the absence of any comments finding errors in our original analysis, we conclude that our estimates on the likely effects of the December 2019 OPO proposed rule may have been reasonable. In this final RIA, we have re-estimated some effects because of the substantive changes made in the final rule, but none of these re-estimates change the main conclusions previously reached on overall costs and benefits of this rule.

C. Effects on OPO Performance

We proposed two new outcome measures that would be used to assess an OPO's performance: A measure of an OPO's donation rate and a measure of its organ transplantation rate in the DSA. In the December 2019 OPO proposed rule, these were two independent tiers that each allowed for only ''pass or fail'' levels of performance. As discussed earlier in the preamble, the final rule now contains a three-tier system for each outcome measure. Table 1 shows current performance using the donation rate outcome measure in this final rule, derived from data spanning January 1, 2018 to December 31, 2018. The final

rule contains a major change in the determination of the donor potential (denominator) for the outcome measures using the CALC methodology for estimating the donor potential as explained in section II.B.6 of the December 2019 OPO proposed rule and in section V.G ''Alternatives Considered'' of this final rule. The CALC measure is endorsed by much of the peer-reviewed literature as technically superior. For the vast majority of OPOs, using the CALC methodology to estimate the denominator does not change their relative performance substantially from that in the December 2019 OPO proposed rule. For example, in Table 13a of the December 2019 OPO proposed rule, we showed that the top 18 performers on donation using the then-proposed measure were also the top 18 performers using the CALC measure. Seventeen of the 20 lowest donation performers on the then-proposed measures were also in the lowest performing group on the CALC measure.

In both the proposed and final rules, the performance variable for the donation rate is the number of actual donors who had at least one organ transplanted, regardless of the number of organs that each provides. This measure focuses on the key tasks of obtaining family consent, clinically managing the donor, and arranging for the actual surgical and handling procedures involved in getting at least one organ from the deceased donor to placement in a patient on a waiting list. Hearts, lungs, livers, kidneys, intestines, and pancreas that are transplanted count towards this measure of success. Additionally, a pancreas that is procured and is used for research or islet cell transplantation also counts for this purpose.

In the tables that follow, the first two digits of the letters in parentheses are, in most cases, the primary state of the OPO. Some OPOs serve more than one state, and some states have more than one OPO. The four digits after the OPO's name represents the digits identifying the DSA and remain unchanged even when the name of the OPO changes. In a few cases in the tables below, we have abbreviated an OPO name to improve simplicity of presentation. For a complete OPO listing and additional information, see the following link: *https://optn.transplant.hrsa.gov/members/member-directory/?memberType=Organ%20Procurement%20Organizations.*[21] These tables show the performance required of each OPO to reach the performance standard, including an allowance for statistical ''confidence'' (one-tailed test), for the OPOs that fell below the standard. Confidence intervals are calculated based on test statistics derived from the assumed binomial and Poisson distribution for the donation rate and transplant rate, respectively. Specifically, the Wilson score interval with continuity correction (Newcombe 1998) is used to calculate the confidence interval for the donation rate of each OPO. The Wilson and Hilferty formula is used to calculate the confidence interval for the transplant rate of each OPO.[22] In lay terms, these confidence levels are simply a way to provide for a ''margin of error'' when calculating the rates for each OPO given the different sizes of the donor potentials.

We are committed to using the best available data to continue our analysis of OPO performance, including, where possible, historical trends in OPO performance; a range of potential outcomes, including a scenario where high performers remain at steady state; and year over year OPO performance and distribution of scores and improvements within the past two certification cycles, using the final rule's outcome measures.

TABLE 1—OPO DONOR RATE FOR 2018 WITH TOP 25% AND MEDIAN CUTOFF LEVELS

[OPOs below Top 25 percent in *italics* and below median in ***bold and italics***]

OPO name	Donation rate	Upper bound with 95% confidence interval	Additional donors to reach median	Additional donors to reach top 25%
Midwest Transplant Network (MWOB)	17.85	19.62	0	0
DonorConnect (UTOP)	15.29	17.65	0	0
Nebraska Organ Recovery System (NEOR)	14.04	17.02	0	0
Gift of Life Donor Program (PADV)	15.59	16.63	0	0
OPO at the U. of Wisconsin (WIUW)	14.24	16.26	0	0
Lifesharing—A Donate Life Organization (CASD)	13.42	15.39	0	0
LifeChoice Donor Services (CTOP)	12.03	14.45	0	0
Nevada Donor Network (NVLV)	12.17	14.01	0	0
OurLegacy (FLFH)	12.42	13.97	0	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	12.84	13.84	0	0
Versiti (WIDN)	11.48	13.74	0	0
Donor Network of Arizona (AZOB)	12.41	13.68	0	0
Lifeshare Carolinas (NCCM)	11.78	13.68	0	0
Donor Alliance (CORS)	12.03	13.65	0	0
The Living Legacy Foundation of Maryland (MDPC)	11.98	13.63	0	0
LifeGift Organ Donation Center (TXGC)	11.96	12.96	0	0
Mid-America Transplant Services (MOMA)	11.27	12.64	0	0
Washington Regional Transplant Community (DCTC)	11.01	12.63	0	0
LifeShare of Oklahoma (OKOP)	11.15	12.56	0	0
ConnectLife (NYWN)	9.75	12.32	0	0
LifeCenter Organ Donor Network (OHOV)	10.18	12.29	0	0
Southwest Transplant Alliance (TXSB)	11.20	12.18	0	0
LifeBanc (OHLB)	10.60	12.05	0	0
Louisiana Organ Procurement Agency (LAOP)	10.72	12.04	0	0
New England Organ Bank (MAOB)	10.82	11.85	0	0
LifeCenter Northwest (WALC)	10.74	11.85	0	0

[21] Some of these OPOs have changed names in recent years, so some other published lists may be out of date. However, the codes shown in parentheses in our tables have not changed.

[22] Wilson and Hilferty 1931, Breslow and Day 1987, Kulkarni and Hemangi 2012.

TABLE 1—OPO DONOR RATE FOR 2018 WITH TOP 25% AND MEDIAN CUTOFF LEVELS—Continued

[OPOs below Top 25 percent in *italics* and below median in ***bold and italics***]

OPO name	Donation rate	Upper bound with 95% confidence interval	Additional donors to reach median	Additional donors to reach top 25%
LifeLink of Puerto Rico (PRLL)	9.95	11.71	0	0
LifeLink of Florida (FLWC)	10.54	11.68	0	0
Gift of Life Michigan (MIOP)	10.50	11.46	0	0
Tennessee Donor Services (TNDS)	10.24	11.25	0	*4*
Life Connection of Ohio (OHLC)	*9.23*	*11.18*	*0*	*2*
LifeLink of Georgia (GALL)	*10.16*	*11.16*	*0*	*6*
Sharing Hope SC (SCOP)	*9.78*	*11.04*	*0*	*6*
Donor Network West (CADN)	*10.05*	*10.99*	*0*	*12*
Legacy of Life (HIOP)	*8.35*	*10.82*	*0*	*3*
Center for Organ Recovery and Education (PATF)	*9.64*	*10.79*	*0*	*12*
Lifeline of Ohio (OHLP)	*9.34*	*10.77*	*0*	*8*
LifeSource—MN (MNOP)	*9.50*	*10.73*	*0*	*12*
New Mexico Donor Services (NMOP)	*8.04*	*10.23*	*0*	*6*
Sierra Donor Services (CAGS)	*8.31*	*10.08*	*0*	*11*
LifeQuest Organ Recovery Services (FLUF)	*8.74*	*9.94*	*0*	*24*
Pacific Northwest Transplant Bank (ORUO)	*8.61*	*9.93*	*0*	*20*
New Jersey Sharing Network OPO (NJTO)	*8.71*	*9.89*	*0*	*26*
Mississippi Organ Recovery Agency (MSOP)	*8.29*	*9.86*	*0*	*15*
Legacy of Hope—Alabama (ALOB)	*8.65*	*9.84*	*0*	*26*
Texas Organ Sharing Alliance (TXSA)	*8.63*	*9.77*	*0*	*30*
Finger Lakes Donor Recovery Network (NYFL)	***7.80***	***9.68***	***1***	***12***
Iowa Donor Network (IAOP)	***7.98***	***9.66***	***1***	***15***
Center for Donation and Transplant (NYAP)	***7.45***	***9.33***	***3***	***14***
LiveOnNY (NYRT)	***8.50***	***9.33***	***13***	***68***
LifeNet Health (VATB)	***7.97***	***9.07***	***12***	***43***
OneLegacy (CAOP)	***8.31***	***8.94***	***43***	***133***
Indiana Donor Network (INOP)	***7.79***	***8.81***	***19***	***54***
Arkansas Regional Organ Recovery Agency (AROR)	***7.06***	***8.69***	***9***	***22***
Carolina Donor Services (NCNC)	***7.58***	***8.52***	***29***	***69***
Kentucky Organ Donor Affiliates (KYDA)	***7.15***	***8.25***	***26***	***54***
Mid-South Transplant Foundation (TNMS)	***6.66***	***8.19***	***14***	***28***
Life Alliance Organ Recovery Agency (FLMP)	***6.87***	***7.86***	***38***	***71***

Note: Cutoffs at 2017 OPO upper bound performance levels of Top 25 percent at 11.37 and median at 9.72.

Table 2 shows the current range of organ transplantation performance, using the new standard of measuring the total number of organs transplanted from deceased donors (including all transplanted organs from each donor) as a percentage of the same donor potential used for the donation rate in the final rule.[23] Table 2 includes both the unadjusted organ transplantation rate and the organ transplantation rate which reflects the rate once it is risk-adjusted for the average age in the donor potential. The organ transplantation rate as defined in § 486.302 will be the basis for re-certification.

According to the NCHS, there are about 2.8 million deaths each year in the U.S., but the potential deceased donor pool is far lower because it only includes those who die in hospitals, who are age 75 or less, and who have primary causes of death consistent with organ donation. As previously discussed, the December 2019 proposed rule used as its measure of donors those inpatient deaths age 75 or less who have no contraindications to donation. We also proposed as an alternative the CALC methodology that uses the same hospital location and age criteria, but uses ICD–10–CM codes reflecting deaths that are consistent with donation—inclusion rather than exclusion. We believe the CALC measure is more widely accepted in the transplant community and now has a body of literature validating its consistency, thus, we have adopted it in this final rule.

As shown in Table 2, the organ transplantation rates range from 57.90 at the highest levels to 18.94 (using data from calendar year 2018), a range of about three to one from highest to lowest. The top-performing OPOs are geographically and demographically diverse, with potential donor pools ranging from about 463 deaths a year to almost 3,566 a year (using the CALC methodology) as shown in Table 1. We recognize that some OPOs have fewer transplant programs within their service areas than others, but allocation policies are no longer based on the DSA and historically, OPOs had access to the organ match run, which lists all potential recipients for a donated organ in the entire country.

[23] These results would look similar if we used the current estimates of ''eligible'' deaths but would be an imperfect comparison since that is not a standardized measure.

TABLE 2—OPO TRANSPLANT RATE FOR 2018 WITH TOP 25% AND MEDIAN CUTOFF LEVELS

[OPOs below top 25 percent in *italics* and below median in ***bold and italics***]

OPO name (primary state)	Organ transplantation rate	Upper bound at 95% CI	Additional organs to reach median	Additional organs to reach top 25%
Nebraska Organ Recovery System (NEOR)	57.90	65.22	0	0
OPO at the U. of Wisconsin (WIUW)	52.92	56.27	0	0
Midwest Transplant Network (MWOB)	52.44	55.29	0	0
Lifesharing—A Donate Life Organization (CASD)	48.49	52.74	0	0
DonorConnect (UTOP)	46.04	49.51	0	0
Nevada Donor Network (NVLV)	45.65	49.28	0	0
LifeLink of Puerto Rico (PRLL)	40.31	44.99	0	0
Gift of Life Donor Program (PADV)	42.04	43.63	0	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	40.57	42.44	0	0
LifeShare of Oklahoma (OKOP)	39.29	42.21	0	0
OurLegacy (FLFH)	39.58	42.17	0	0
Gift of Life Michigan (MIOP)	39.43	41.46	0	0
LifeGift Organ Donation Center (TXGC)	39.20	41.03	0	0
Center for Organ Recovery and Education (PATF)	38.24	40.83	0	0
Donor Network of Arizona (AZOB)	38.22	40.09	0	0
The Living Legacy Foundation of Maryland (MDPC)	36.24	38.64	0	0
LifeLink of Florida (FLWC)	36.40	38.63	0	0
Donor Network West (CADN)	36.04	37.90	0	0
Washington Regional Transplant Community (DCTC)	35.39	37.83	0	0
LifeCenter Northwest (WALC)	35.76	37.72	0	0
LiveOnNY (NYRT)	35.49	37.70	0	0
Versiti (WIDN)	33.95	37.45	0	0
LifeBanc (OHLB)	34.74	37.27	0	0
Southwest Transplant Alliance (TXSB)	35.29	37.00	0	0
Lifeshare Carolinas (NCCM)	33.72	36.51	0	0
Mid-America Transplant Services (MOMA)	34.36	36.49	0	0
New England Organ Bank (MAOB)	34.45	36.30	0	0
Tennessee Donor Services (TNDS)	*34.18*	*36.04*	*0*	*2*
LifeChoice Donor Services (CTOP)	*32.17*	*35.53*	*0*	*4*
Sierra Donor Services (CAGS)	*31.69*	*35.25*	*0*	*7*
New Jersey Sharing Network OPO (NJTO)	*32.75*	*35.18*	*0*	*15*
Louisiana Organ Procurement Agency (LAOP)	*32.74*	*34.86*	*0*	*23*
ConnectLife (NYWN)	*30.17*	*34.63*	*0*	*7*
LifeLink of Georgia (GALL)	*31.69*	*33.42*	*0*	*75*
Pacific Northwest Transplant Bank (ORUO)	*30.65*	*33.31*	*0*	*36*
Lifeline of Ohio (OHLP)	*30.14*	*32.56*	*0*	*47*
Center for Donation and Transplant (NYAP)	*28.06*	*32.51*	*0*	*18*
LifeSource—MN (MNOP)	*30.23*	*32.27*	*0*	*71*
Iowa Donor Network (IAOP)	*29.11*	*32.23*	*0*	*32*
OneLegacy (CAOP)	*30.88*	*32.18*	*0*	*202*
Legacy of Hope—Alabama (ALOB)	***29.04***	***31.34***	***12***	***75***
Mississippi Organ Recovery Agency (MSOP)	***28.21***	***31.22***	***8***	***44***
Donor Alliance (CORS)	***29.26***	***31.15***	***15***	***81***
Texas Organ Sharing Alliance (TXSA)	***28.57***	***30.48***	***31***	***110***
Life Connection of Ohio (OHLC)	***27.26***	***30.02***	***17***	***50***
Sharing Hope SC (SCOP)	***28.05***	***29.89***	***42***	***120***
LifeNet Health (VATB)	***27.65***	***29.68***	***44***	***117***
Finger Lakes Donor Recovery Network (NYFL)	***26.16***	***29.30***	***19***	***47***
LifeCenter Organ Donor Network (OHOV)	***26.44***	***29.00***	***26***	***60***
Arkansas Regional Organ Recovery Agency (AROR)	***25.80***	***28.85***	***25***	***56***
Carolina Donor Services (NCNC)	***26.82***	***28.62***	***80***	***173***
LifeQuest Organ Recovery Services (FLUF)	***26.55***	***28.50***	***63***	***134***
Legacy of Life (HIOP)	***22.91***	***27.01***	***20***	***35***
New Mexico Donor Services (NMOP)	***23.53***	***26.80***	***29***	***51***
Indiana Donor Network (INOP)	***25.06***	***26.58***	***135***	***236***
Kentucky Organ Donor Affiliates (KYDA)	***24.17***	***26.00***	***110***	***184***
Life Alliance Organ Recovery Agency (FLMP)	***23.81***	***25.59***	***130***	***211***
Mid-South Transplant Foundation (TNMS)	***18.94***	***21.05***	***109***	***149***
Totals	.....	.....	915	2,472

Note: Cutoffs at 2017 OPO upper bound performance levels of Top 25% at 36.10 and median at 32.05.

Both outcome measures as originally proposed and in the final rule address multiple goals not met by the current requirements: (1) They can be uniformly applied across all OPOs; (2) they capture not only success in obtaining donors but also success in placing as many organs as possible; (3) they capture virtually the entire pool of possible donors (not the pool as determined separately by each OPO); (4) they adjust for the geographic

differences in the number and causes of death; and (5) they meet central necessities for a workable performance standard that exhibits uniformity, timeliness, and stability year-to-year. Of particular importance, these measures, both as proposed and as made final, would replace the subjective and self-reported criteria of eligible donors and eligible deaths. The existing denominator standard allows OPOs to exclude from the calculated potential donor pool those cases where the next-of-kin did not authorize donation, a crucial task we believe all OPOs should be effective and continually improving at. For an extensive discussion of these and related issues, see ''Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States.'' [24] The proposed and final measures do not control for every variable that can affect OPO performance for reasons beyond its control. For example, states without motorcycle helmet laws have higher rates of accidents that create potential donors. Some DSAs have greater transplant hospital competition than others, and more competition for transplantable organs is associated with greater use of organs that might otherwise be discarded.[25] Regardless, it is our belief that the untapped donor and organ potential is sufficiently large in every DSA so that every OPO has both potential donors, organs, and transplant recipients to exceed its current performance level. We received no public comments presenting evidence to the contrary.

One way to understand the potential is to compare current donation rates with the CALC methodology used to calculate potential donors in the final rule, a very important quantitative result: In 2018 there were about 10,000 deceased donors, which is only about 10 percent of the almost 100,000 potential donors in 2018 (*https://srtr.transplant.hrsa.gov/annual_reports/2018/DOD.aspx*). The highest performing OPOs at present do not quite reach a rate of 20 percent of potential donors becoming actual donors. Importantly, the final rule's criteria for potential donors already exclude most deaths, and focus on decedents with substantial potential to provide transplantable organs. Hence, all OPOs have a pool of potential donors many times higher than the number of donors and organs needed to meet the final rule's performance standards. Furthermore, in 2018, there were 1,073,084 death and imminent death referrals reported to the OPTN by OPOs,[26] meaning that less than 1 percent of referrals became organ donors.

If the number of donors at the Tier 2 and Tier 3 OPOs were to reach the threshold rate of the top 25 percent, the number of annual donors would increase by approximately one thousand by the end of the 4-year performance period and increase the number of organ transplantations by about 2,500. As show in Tables 4 and 5, both donors and transplants could be far higher than these thresholds with as little as a 20 percent overall rate of improvement over a 5-year period.

We believe that all OPOs are capable of achieving these higher success rates; our estimates assume improvements at all current levels of performance due to better techniques and methods associated with organ procurement as well as the ''incentives'' provided to the top performing OPOs (that is, keeping their DSA free from competition and allowing them to compete for an open new DSA). For example, there have been major recent improvements in perfusion techniques used to preserve kidneys and extend the time period allowed between donation and transplantation. This technology rewards focusing efforts on extending the placement of organs beyond local areas for appropriate transplant candidates on waiting lists. These techniques are available to all OPOs, but have not been adopted by all. While there may be future improvements,[27] our estimates do not factor in potential future major breakthroughs.

TABLE 3—OPO RATINGS AND TIERS FOR BOTH DONATION AND TRANSPLANT RATES

[OPOs below top 25 percent in *Italics* and below median in ***bold and italics***]

OPO name (primary state)	Donation rate	95% CI	Organ transplant rate	95% CI	Tier
Nebraska Organ Recovery System (NEOR)	14.04	17.02	57.90	65.22	Tier 1.
OPO at the U. of Wisconsin (WIUW)	14.24	16.26	52.32	56.27	
Midwest Transplant Network (MWOB)	17.85	19.62	52.44	55.29	
Lifesharing—A Donate Life Organization (CASD)	13.42	15.39	48.49	52.74	
DonorConnect (UTOP)	15.29	17.65	46.04	49.51	
Nevada Donor Network (NVLV)	12.17	14.01	45.65	49.28	
LifeLink of Puerto Rico (PRLL)	9.95	11.71	40.31	44.99	
Gift of Life Donor Program (PADV)	15.59	16.63	42.04	43.63	
Gift of Hope Organ & Tissue Donor Network (ILIP)	12.84	13.84	40.57	42.44	
LifeShare of Oklahoma (OKOP)	11.15	12.56	39.29	42.21	
OurLegacy (FLFH)	12.42	13.97	39.58	42.17	
Gift of Life Michigan (MIOP)	10.50	11.46	39.43	41.46	
LifeGift Organ Donation Center (TXGC)	11.96	12.96	39.20	41.03	
Donor Network of Arizona (AZOB)	12.41	13.68	38.22	40.09	
The Living Legacy Foundation of Maryland (MDPC)	11.98	13.63	36.24	38.64	
LifeLink of Florida (FLWC)	10.54	11.68	36.40	38.63	
Washington Regional Transplant Community (DCTC)	11.01	12.63	35.39	37.83	
LifeCenter Northwest (WALC)	10.74	11.85	35.76	37.72	
Versiti (WIDN)	11.48	13.74	33.95	37.45	
LifeBanc (OHLB)	10.60	12.05	34.74	37.27	

[24] Goldberg D, et al., ''Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States,'' *Am J Transplant* 2017; 17:3183–3192.

[25] Adler, et al. ''Is Donor Service Area Market Competition Associated with Organ Procurement Organization Performance?'' *Transplantation* 2016; 100; 1349–1355.

[26] OPTN 2018 Annual Report, *https://srtr.transplant.hrsa.gov/annual_reports/2018/DOD.aspx.*

[27] *https://www.nih.gov/news-events/news-releases/scientists-triple-storage-time-human-donor-livers.*

TABLE 3—OPO RATINGS AND TIERS FOR BOTH DONATION AND TRANSPLANT RATES—Continued

[OPOs below top 25 percent in *Italics* and below median in ***bold and italics***]

OPO name (primary state)	Donation rate	95% CI	Organ transplant rate	95% CI	Tier
Southwest Transplant Alliance (TXSB)	11.20	12.18	35.29	37.00	
Lifeshare of the Carolinas (NCCM)	11.78	13.68	33.72	36.51	
Mid-America Transplant Services (MOMA)	11.27	12.64	34.36	36.49	
New England Organ Bank (MAOB)	10.82	11.85	34.45	36.30	
Center for Organ Recovery and Education (PATF)	*9.64*	*10.79*	38.24	40.83	Tier 2.
Donor Network West (CADN)	*10.05*	*10.99*	36.04	37.90	
Tennessee Donor Services (TNDS)	*10.24*	*11.25*	*34.18*	*36.04*	
LifeChoice Donor Services (CTOP)	12.03	14.45	*32.17*	*35.53*	
Sierra Donor Services (CAGS)	*8.31*	*10.08*	*31.69*	*35.25*	
New Jersey Sharing Network OPO (NJTO)	*8.71*	*9.89*	*32.75*	*35.18*	
Louisiana Organ Procurement Agency (LAOP)	10.72	12.04	*32.74*	*34.86*	
ConnectLife (NYWN)	9.75	12.32	*30.17*	*34.63*	
LifeLink of Georgia (GALL)	*10.16*	*11.16*	*31.69*	*33.42*	
Pacific Northwest Transplant Bank (ORUO)	*8.61*	*9.93*	*30.65*	*33.31*	
Lifeline of Ohio (OHLP)	*9.34*	*10.77*	*30.14*	*32.56*	
LifeSource—MN (MNOP)	*9.50*	*10.73*	*30.23*	*32.27*	
LiveOnNY (NYRT)	***8.50***	***9.33***	35.49	37.70	Tier 3.
Center for Donation and Transplant (NYAP)	***7.45***	***9.33***	*28.06*	*32.51*	
Iowa Donor Network (IAOP)	***7.98***	***9.66***	*29.11*	*32.23*	
OneLegacy (CAOP)	***8.31***	***8.94***	*30.88*	*32.18*	
Legacy of Hope—Alabama (ALOB)	*8.65*	*9.84*	*29.04*	*31.34*	
Mississippi Organ Recovery Agency (MSOP)	*8.29*	*9.86*	***28.21***	***31.22***	
Donor Alliance (CORS)	12.03	13.65	***29.26***	***31.15***	
Texas Organ Sharing Alliance (TXSA)	*8.63*	*9.77*	***28.57***	***30.48***	
Life Connection of Ohio (OHLC)	*9.23*	*11.18*	***27.26***	***30.02***	
Sharing Hope SC (SCOP)	*9.78*	*11.04*	***28.05***	***29.89***	
LifeCenter Organ Donor Network (OHOV)	10.18	12.29	***26.44***	***29.00***	
LifeQuest Organ Recovery Services (FLUF)	*8.74*	*9.94*	***26.55***	***28.50***	
Legacy of Life (HIOP)	*8.35*	*10.82*	***22.91***	****27.01***	
New Mexico Donor Services (NMOP)	*8.04*	*10.23*	***23.53***	***26.80***	
LifeNet Health (VATB)	***7.97***	***9.07***	***27.65***	***29.68***	
Finger Lakes Donor Recovery Network (NYFL)	***7.80***	***9.68***	***26.16***	***29.30***	
Arkansas Regional Organ Recovery Agency (AROR)	***7.06***	***8.69***	***25.80***	***28.85***	
Carolina Donor Services (NCNC)	***7.58***	***8.52***	***26.82***	***28.62***	
Indiana Donor Network (INOP)	***7.79***	***8.81***	***25.06***	***26.58***	
Kentucky Organ Donor Affiliates (KYDA)	***7.15***	***8.25***	***24.17***	***26.00***	
Life Alliance Organ Recovery Agency (FLMP)	***6.87***	***7.86***	***23.81***	***25.59***	
Mid-South Transplant Foundation (TNMS)	***6.66***	***8.19***	***18.94***	***21.05***	

Note: For donors top 25 percent cutoff level at 11.37 and median at 9.72; for transplants at 36.10 and 32.05.

* Hawaii OPO's kidney transplantation rate will be used instead of the organ transplantation rate. It was in Tier 1 for kidney transplantations.

Table 3 shows the combined results of the donation and organ transplantation rates and the tier assignment for each OPO. As seen by the markings in bold and italics, many OPOs are high or low on both outcome measures. Within the Tier 2 cohort, 8 of the 26 OPOs made it to Tier 2 based on performance on the donation rate only (because their organ transplantation rates were in Tier 3), whereas only 4 OPOs made it to Tier 2 based on their organ transplantation rates (because their donation rates were in Tier 3). This difference suggests that it may be easier for OPOs to reach Tier 2 through the donation rate—possibly by pursuing and successfully placing organs from the extended criteria donors. There only were only 12 OPOs whose donation and organ/kidney transplantation rates were at or above the median threshold rate, but not in Tier 1. Some OPOs were in Tier 1 on the donation rate, yet Tier 3 in the organ transplantation rate, suggesting that OPOs could do more to strengthen their organ placement practices. Those OPOs with higher performance in their organ transplantation rate than their donation rate could increase their donation rates by increasing their single organ donors.

Our estimates in Tables 4 (donors) and 5 (transplants) show what would be required for all OPOs to achieve either the median rate, the threshold rate of the top 25 percent, or an increase in performance by 20 percent or to the rate of the top 25 percent, whichever is greater. (While not every OPO would make the same percentage gain, any combination of gains reaching the ''greater of'' estimate on average would produce the same total gains.) The importance of these estimates is not the exact numbers, but rather that even the currently best-performing OPOs can increase performance over time with concomitant improvements in techniques and technology, and will face strong incentives to do so or risk losing their place in the top 25 percent.

TABLE 4—ADDITIONAL DONORS TO REACH MEDIAN, TOP 25%, OR GREATER OF TOP 25% OR 20%

OPO name (primary state)	Additional donors to reach:				
	Potential donors (2018)	Actual donors (2018)	Median	Top 25%	Higher of top 25% or 20% more
Midwest Transplant Network (MWOB)	1,423	254	0	0	51
DonorConnect (UTOP)	752	115	0	0	23
Nebraska Organ Recovery System (NEOR)	463	65	0	0	13
Gift of Life Donor Program (PADV)	3,566	556	0	0	111
OPO at the U. of Wisconsin (WIUW)	955	136	0	0	27
Lifesharing—A Donate Life Organization (CASD)	954	128	0	0	26
LifeChoice Donor Services (CTOP)	615	74	0	0	15
Nevada Donor Network (NVLV)	1,011	123	0	0	25
OurLegacy (FLFH)	1,417	176	0	0	35
Gift of Hope Organ & Tissue Donor Network (ILIP)	3,302	424	0	0	85
Versiti (WIDN)	671	77	0	0	15
Donor Network of Arizona (AZOB)	2,039	253	0	0	51
Lifeshare Carolinas (NCCM)	934	110	0	0	22
Donor Alliance (CORS)	1,272	153	0	0	31
The Living Legacy Foundation of Maryland (MDPC)	1,219	146	0	0	29
LifeGift Organ Donation Center (TXGC)	3,145	376	0	0	75
Mid-America Transplant Services (MOMA)	1,659	187	0	0	37
Washington Regional Transplant Community (DCTC)	1,190	131	0	0	26
LifeShare of Oklahoma (OKOP)	1,561	174	0	0	35
ConnectLife (NYWN)	482	47	0	0	9
LifeCenter Organ Donor Network (OHOV)	707	72	0	0	14
Southwest Transplant Alliance (TXSB)	3,090	346	0	0	69
LifeBanc (OHLB)	1,443	153	0	0	31
Louisiana Organ Procurement Agency (LAOP)	1,717	184	0	0	37
New England Organ Bank (MAOB)	2,790	302	0	0	60
LifeCenter Northwest (WALC)	2,420	260	0	0	52
LifeLink of Puerto Rico (PRLL)	955	95	0	0	19
LifeLink of Florida (FLWC)	2,248	237	0	0	47
Gift of Life Michigan (MIOP)	3,057	321	0	0	64
Tennessee Donor Services (TNDS)	2,735	280	0	4	56
Life Connection of Ohio (OHLC)	758	70	0	2	14
LifeLink of Georgia (GALL)	2,795	284	0	6	57
Sharing Hope SC (SCOP)	1,749	171	0	6	34
Donor Network West (CADN)	3,086	310	0	12	62
Legacy of Life (HIOP)	467	39	0	3	8
Center for Organ Recovery and Education (PATF)	2,044	197	0	12	39
Lifeline of Ohio (OHLP)	1,328	124	0	8	25
LifeSource—MN (MNOP)	1,810	172	0	12	34
New Mexico Donor Services (NMOP)	560	45	0	6	9
Sierra Donor Services (CAGS)	842	70	0	11	14
LifeQuest Organ Recovery Services (FLUF)	1,751	153	0	24	31
Pacific Northwest Transplant Bank (ORUO)	1,463	126	0	20	25
New Jersey Sharing Network OPO (NJTO)	1,792	156	0	26	31
Mississippi Organ Recovery Agency (MSOP)	1,037	86	0	15	17
Legacy of Hope—Alabama (ALOB)	1,781	154	0	26	31
Texas Organ Sharing Alliance (TXSA)	1,913	165	0	30	33
Finger Lakes Donor Recovery Network (NYFL)	718	56	1	12	12
Iowa Donor Network (IAOP)	890	71	1	15	15
Center for Donation and Transplant (NYAP)	698	52	3	14	14
LiveOnNY (NYRT)	3,435	292	13	68	68
LifeNet Health (VATB)	1,945	155	12	43	43
OneLegacy (CAOP)	5,634	468	43	133	133
Indiana Donor Network (INOP)	2,183	170	19	54	54
Arkansas Regional Organ Recovery Agency (AROR)	864	61	9	22	22
Carolina Donor Services (NCNC)	2,506	190	29	69	69
Kentucky Organ Donor Affiliates (KYDA)	1,803	129	26	54	54
Mid-South Transplant Foundation (TNMS)	931	62	14	28	28
Life Alliance Organ Recovery Agency (FLMP)	2,111	145	38	71	71
Totals	98,686	10,128	208	806	2,238

Nothing guarantees that all OPOs will manage to meet the final rule outcome measures. Nevertheless, the administrative steps we propose to take, the periodic assessments, and the incentives for an OPO to maintain certification at the end of the 4-year evaluation period provide both means and incentives for all OPOs to meet or exceed our standards. Moreover, there are three additional reasons to expect performance increases (if any) to occur

in all three tiers. First, Tier 1 OPOs near the Tier 2 boundary will be concerned about maintaining ongoing performance levels high enough to guarantee Tier 1 performance at their final assessment period—since other OPOs may be achieving higher performance levels. Second, only by aiming higher than the minimum needed to gain or remain in Tier 1 earlier in the final assessment period, is it possible to ensure that unexpected decreases at the end of the final assessment period do not result in loss of Tier 1 status. Third, there may be emerging best practices in both areas of performance that can be applied widely by all OPOs. For example, a current Tier 3 OPO could implement a specific management reform or operational innovation that substantially increases performance in increasing consent for donation. If the effects of this change are observed broadly, then the innovation could be adopted by others. While such an effective best practice could also reduce the likelihood of sharing such best practices, particularly for OPOs on the margins every OPO able to see the published annual performance results of all OPOs, and performance improvements or lack thereof will be readily apparent. Formal and informal communication channels would in any event prevent suppression of information on better practices.

With continuous assessment and public disclosure of the information, OPOs that cannot achieve the outcome measures may decide to voluntarily de-certify and allow a high-performing OPO take over the DSA, even before the end of the 4 year re-certification cycle, or form a partnership with a high-performing OPO and allow that OPO to take over the management of the DSA, most likely through a merger or friendly takeover. Both our low-end and higher cost and performance calculations assume that this could be avoided through adoption of proven techniques and improved leadership and management by lower-performing OPOs. Careful planning and implementation of OPO de-certifications and OPO DSA competitions could ease such transitions, but each performance level can be reached or exceeded, or maintained, by constant OPO management improvements. The new outcome measures and performance expectations may give each OPO both the opportunity and incentives to assess its performance, innovate, and adopt best practices.

TABLE 5—ADDITIONAL ORGAN TRANSPLANTS TO REACH MEDIAN, TOP 25%, OR GREATER OF TOP 25% OR 20%

OPO name (primary state)	Additional transplants to reach:			
	Actual transplants (2018)	Median	Top 25%	Higher of top 25% or 20% more
Nebraska Organ Recovery System (NEOR)	213	0	0	43
OPO at the U. of Wisconsin (WIUW)	487	0	0	97
Midwest Transplant Network (MWOB)	825	0	0	165
Lifesharing—A Donate Life Organization (CASD)	404	0	0	81
DonorConnect (UTOP)	406	0	0	81
Nevada Donor Network (NVLV)	445	0	0	89
LifeLink of Puerto Rico (PRLL)	278	0	0	56
Gift of Life Donor Program (PADV)	1,688	0	0	338
Gift of Hope Organ & Tissue Donor Network (ILIP)	1,305	0	0	261
LifeShare of Oklahoma (OKOP)	548	0	0	110
OurLegacy (FLFH)	597	0	0	119
Gift of Life Michigan (MIOP)	1,106	0	0	221
LifeGift Organ Donation Center (TXGC)	1,240	0	0	248
Center for Organ Recovery and Education (PATF)	680	0	0	136
Donor Network of Arizona (AZOB)	934	0	0	187
The Living Legacy Foundation of Maryland (MDPC)	521	0	0	104
LifeLink of Florida (FLWC)	766	0	0	153
Donor Network West (CADN)	1,062	0	0	212
Washington Regional Transplant Community (DCTC)	490	0	0	98
LifeCenter Northwest (WALC)	883	0	0	177
LiveOnNY (NYRT)	923	0	0	185
Versiti (WIDN)	241	0	0	48
LifeBanc (OHLB)	505	0	0	101
Southwest Transplant Alliance (TXSB)	1,126	0	0	225
Lifeshare Carolinas (NCCM)	354	0	0	71
Mid-America Transplant Services (MOMA)	634	0	0	127
New England Organ Bank (MAOB)	946	0	0	189
Tennessee Donor Services (TNDS)	922	0	2	184
LifeChoice Donor Services (CTOP)	221	0	4	44
Sierra Donor Services (CAGS)	239	0	7	48
New Jersey Sharing Network OPO (NJTO)	538	0	15	108
Louisiana Organ Procurement Agency (LAOP)	604	0	23	121
ConnectLife (NYWN)	134	0	7	27
LifeLink of Georgia (GALL)	898	0	75	180
Pacific Northwest Transplant Bank (ORUO)	401	0	36	80
Lifeline of Ohio (OHLP)	410	0	47	82
Center for Donation and Transplant (NYAP)	145	0	18	29
LifeSource—MN (MNOP)	572	0	71	114
Iowa Donor Network (IAOP)	247	0	32	49
OneLegacy (CAOP)	1,625	0	202	325
Legacy of Hope—Alabama (ALOB)	472	12	75	94
Mississippi Organ Recovery Agency (MSOP)	264	8	44	53
Donor Alliance (CORS)	491	15	81	98

TABLE 5—ADDITIONAL ORGAN TRANSPLANTS TO REACH MEDIAN, TOP 25%, OR GREATER OF TOP 25% OR 20%—Continued

OPO name (primary state)	Additional transplants to reach:			
	Actual transplants (2018)	Median	Top 25%	Higher of top 25% or 20% more
Texas Organ Sharing Alliance (TXSA)	574	31	110	115
Life Connection of Ohio (OHLC)	233	17	50	50
Sharing Hope SC (SCOP)	555	42	120	120
LifeNet Health (VATB)	521	44	117	117
Finger Lakes Donor Recovery Network (NYFL)	188	19	47	47
LifeCenter Organ Donor Network (OHOV)	232	26	60	60
Arkansas Regional Organ Recovery Agency (AROR)	208	25	56	56
Carolina Donor Services (NCNC)	638	80	173	173
LifeQuest Organ Recovery Services (FLUF)	482	63	134	134
Legacy of Life (HIOP)	95	20	35	35
New Mexico Donor Services (NMOP)	136	29	51	51
Indiana Donor Network (INOP)	636	135	236	236
Kentucky Organ Donor Affiliates (KYDA)	454	110	184	184
Life Alliance Organ Recovery Agency (FLMP)	493	130	211	211
Mid-South Transplant Foundation (TNMS)	196	109	149	149
Subtotal Transplants plus Pancreata Research	33,431	915	2,472	7,296
Total Actual Transplants	32,852	899	2,429	7,169

The characteristics of the organ procurement ''market'' are unusual because it was established as a system of private monopolies by statute (NOTA). OPOs are part of the supply chain for final goods—organs for transplant—that are not transacted in a market (in the sense of a good's price being the mechanism whereby the quantity supplied and the quantity demanded achieve equality), and therefore care must be taken in using concepts such as market competition or equilibrium. In another example from the health care sector, which may provide a somewhat more appropriate extrapolation for purposes of this regulatory impact analysis than would results from other contexts with more standard market goods and services, one study found that many hospitals in the English public hospital system faced closure due to potential electoral defeat of their political party protectors in particular geographic areas vulnerable to election swings. To avoid the risk of being the hospital to be closed, hospitals in these situations improved both management practices and medical care performance (measured by reductions in death rates from heart attacks).[28] While it is impossible to predict future achievement levels with any certainty from the impact of introducing significantly more competition into any particular monopolistic market (if this rule indeed avoids bringing about the potential consolidation noted above and the transaction frictions noted below), we have developed a hypothetical scenario for the first 4 years of competition that we believe is consistent with the results from other situations where large numbers of organizations faced potential closure. This scenario would nearly achieve about half of HHS' 2030 target of doubling kidneys available for transplantation (with 4 years remaining to attain that actual goal); and we can use it in estimating benefits and costs while allowing for either higher or lower results.

From the estimates in Tables 4 and 5, we assume that on average, OPOs may improve their organ procurement and transplantation performances by more than the minimums necessary to retain their DSAs with a margin for error. Striving for organizational survival as well as for professional and life-saving achievements are strong motivations to improve performance not only to the exact level needed for organizational survival, but also to allow for a margin of error. These projections are estimates and subject to change based on future events and decisions, but fall within the improvement ranges seen in recent years in some OPOs, as well as the consistently high performance levels in many OPOs. Additionally, for these projections, we assume CMS monitors OPO performance as frequently as every 12 months, using nationally consistent and timely data in both the numerator and denominator of performance measures, and intervening with QAPI requests when performance lags. Finally, these projections reflect the direct incentives to both OPOs and transplant hospitals to improve donation and transplantation rates from older donors to older patients, which ultimately facilitate the utilization of the large number of currently discarded, but transplantable, organs. For example, a transplant program that chooses to bypass a transplant quality organ from either its local OPO or some other OPO is also bypassing the revenues from the transplantation of that organ. Since the supply of organs is finite and limited, and many patients die while awaiting transplants, that lost revenue may never be replaced. Furthermore, the recent elimination of the potential for termination of transplant programs that did not achieve the highest possible success rates removes a strong disincentive for accepting and using all transplant quality organs.

Unfortunately, there are many unknowns that impede predicting future outcomes under this final rule. In our most optimistic scenario, about 85 percent of all potential donors would still be potential rather than actual donors. These potential donors are concentrated among those in the age range of 55 to 75, but the vast majority could provide organs of transplant quality if donated. That said, this potential has been obvious for many years, and progress has been inexplicably slow—inexplicably slow except for the now-recently removed threat to survival for transplant

[28] Nicholas Bloom et al., The Impact of Competition on Management Quality: Evidence from Public Hospitals, Review of Economic Studies, 2015, at *https://nbloom.people.stanford.edu/sites/g/files/sbiybj4746/f/bpsv.pdf.*

programs that did not achieve the highest possible success rates. In this regard, it is important to note that according to OPTN and NCHS mortality data, donation rates are highest among the young and far lower among potential donors in their 50s, 60s, and early 70s.[29]

More broadly, there were about 10,000 deceased donors in 2018. The highest tenth of OPOs (six of the 58) had an average donation rate of about 14 percent, and the lowest tenth (six of the 58) of about 7 percent. Assuming that this higher level is potentially attainable in any DSA, under ideal circumstances, the total number of donors could increase by about half, to about 15,000—much higher than we project in our high performance scenario. There is no reason to assume that 14 percent is an upper limit for the donation rate, given that there are potentially 100,000 donors every year. That said, it cannot be assumed that all OPOs can match the performance of the top tenth within a 4-year period. Therefore, for purposes of describing a hypothetical level of performance by the end of the second re-certification cycle, in subsequent tables and estimates, we assume that the average donation rate may increase by about 20 percent—from 10,000 to 12,000 donors.

We make a similar set of assumptions for the organ transplantation rate performance measure. In 2018, there were about 33,000 transplants from deceased donors. As shown in Table 2, there is more than a two to one difference between the top tenth (6 out of 58) and the lowest tenth: From an average rate of about 48 percent to about 22 percent. On average, there were about 3.3 organs transplanted per donor. The number of organs transplanted per donor varied widely, from an average of about 3.6 for the top tenth to about 2.8 for the bottom tenth. Assuming a 20 percent increase in number of donors and a 5 percent increase in organs per donor (to an average of 3.45), the number of annual organs transplanted would hypothetically rise from about 33,000 in 2018 to about 41,000 (12,000 $\times$ 3.45) by 2026 (Table 5 shows transplant increases not including the 5 percent increase, with the total growing to about 40,000).

While there is no certainty that these or similar levels of performance will be realized, there is additional evidence beyond the known performance levels of the higher-achieving OPOs. As discussed in the December 2019 OPO proposed rule, the discard rate for kidneys in France has been about half the rate in the U.S., under rules that rewarded rather than penalized using higher risk organs.[30] While most European countries use mandatory nation-wide ''opt-out'' rather than ''opt-in'' policies and hence more strongly encourage organ donation than in the U.S. (where no states use ''opt-out''), a recent study shows that this policy does not explain European success rates and that many American states have organ donation rates higher than many European countries.[31] One important policy difference that does seem to matter is that in France, as in most other European countries, organs from older donors are systematically matched for use by older patients, without penalizing transplant programs for the lower success rates that inevitably result.[32] Performance results such as those achieved in France could be achievable in the U.S. with greater accountability for OPO performance, due to some combination of the removal of the outcome measures that penalized transplant programs that do not achieve their risk-adjusted expected 1-year graft and patient survival outcomes; and payment reform. The October 1, 2020 implementation of a new Medicare Severity-Diagnosis Related Groups (MS–DRGs) for kidney transplants with hemodialysis during the same stay (DRG 019; DRG 650 and DRG 651) raises payments in these cases, such that the increased costs associated with transplanting higher-risk kidneys is less of a financial disincentive.

We also have additional evidence from the U.S. that was not available at the time we proposed this rule. We now know that there were major gains in numbers of kidney transplants from 2017 to 2018. Moreover, there appears to have been another major increase in 2019. According to a recent summary from UNOS, the number of deceased organ donors increased by over 10 percent in 2019; 48 OPOs increased the total number of donors in 2019 over the previous year, and 41 OPOs set their all-time organ donation record in 2019.[33] It will be some time before the various potential reasons for these increases can be determined. However, from what we are able to ascertain, these data demonstrate that the problem this rule is meant to address has already been lessened, possibly in part due to earlier regulatory interventions.

As discussed earlier in the preamble, we have considered the effects of COVID–19 on the time of the new standards imposed in this rule. The implementation of the rule may be slowed by a year, as a result of COVID–19. In terms of effects on donation and transplantation rates over time, we expect those to be minimal and possibly not even detectable in future data. The numbers of deaths and severe illnesses among younger Americans have been less than from the annual influenza virus. Among the elderly over the age of 75, who are by orders of magnitude the age group most severely affected by morbidity and mortality from COVID–19, both donations and transplants were rare before COVID–19 and will remain so with no particular COVID effect. We are not saying that there will be no effects leading to changes in donation and transplantation practices or results; simply that these will be very small in relation to the number of potential and actual donors and to the number of potential and actual transplant recipients.

D. Anticipated Costs and Benefits

There are intrinsic connections between the costs and benefits examined in this section. Consider, for instance, the relatively low costs for OPOs and other entities in the health care industry (discussed in the subsequent discussion of ''Implementation and Continuing Costs''). Such low costs are plausible if OPO de-certifications are rare, which could occur if enforcement is lax; if all or a significant portion of OPOs achieve the threshold rate of the top 25 percent; or if the potential for de-certification results in mergers or voluntary takeovers. Without strong enforcement, OPO behavior change may be minimal, in which case low costs would be accompanied by low longevity benefits and medical expenditure impacts (significantly lower than the estimates appearing in Tables 10 and 13).

On the other end of the spectrum, if the competition and the potential for de-certification motivates substantial improvements, this would make substantial benefits and cost plausible. Foreseeable technological advances that we have not included in our analysis could also lead to substantial volume increases and resulting increases in both costs and benefits.

In any scenario, OPOs undergoing such management change experience

[29] Organ donors <50 make up approximately 67 percent of donors, but make up less than 10 percent of deaths.

[30] Olivier Aubert et al., ''Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased U.S. Acceptance,'' *JAMA Intern Med.* Doi:10:1001/jamainternmed.2019.2322.

[31] Alexandra Glazier and Thomas Mone, ''Success in Opt-In Organ Donation Policy in the United States,'' August 8, 2019, doi:10.1001/*JAMA*.2019.9187.

[32] See Olivier Aubert, et al.

[33] See the following link at the UNOS website: *https://unos.org/transplant/opos-increasing-organ-donation/*.

difficult to quantify, transition costs including those related to changing a chief executive officer and/or board of directors, as well as cases involving litigation and prolonged management uncertainty, which could pose potentially much larger administrative and management costs in a few cases than those we have projected. Broader societal transition costs could include reduced organ recovery while the de-certification process unfolds, even if improved practices increase transplant activity in the medium- to long-term. It may be the case that some boards of directors of low-performing OPOs, recognizing that major improvement is unlikely under current top management, replace those employees during the period before the de-certification deadline with proven managers from highly effective OPOs. The annual assessments conducted as part of this final rule and the creation of a publicly available tier ranking of OPO performance using objective data will provide OPO Boards the necessary information to make this type of decision. In either case, we would expect that most OPO operations would continue with operational reforms, but with few if any lower-level staff being replaced and a small number of higher-level managers being replaced.

We expect no costs for disruption of actual organ procurement at any OPOs for two reasons. First, we believe that almost all OPOs will be able to comply with the new tiered standards or will arrange a friendly merger with another OPO. There is no reason to expect performance disruption from a change in top leadership in such cases. In the relative handful of cases where the OPO is actually decertified and replaced, the newly responsible OPO would presumably arrange a smooth continuation of services in the DSA through negotiations with the outgoing Board of Directors and CEO to retain existing staff. No public comments suggested that any more disruptive outcome would ever be likely.

1. *Effects on Medical Costs.* In the estimates that follow, we rely primarily on recent estimates by staff of the actuarial and consulting firm Milliman. Their study, ''2017 U.S. Organ and Tissue Transplant Cost Estimates and Discussion'' compares charges before, during, and after transplantation for all major and minor categories of transplant.[34] The advantage of these estimates for our purposes is that they cover the pre-, intra-, and post-transplant costs on all organs using a consistent cost-estimating methodology. Unfortunately, accurate medical cost estimates are not publicly available from health insurance firms, since the network discounts received by private firms are generally treated as trade secrets, and Medicare's payments are typically not based directly on costs (with some exceptions, including payments to OPOs). Hence, Milliman uses ''charges'' for its estimates. As with likely excess of charges over costs, there is a netting off of non-transplantation costs—that is, costs associated with organ failure that are not affected by transplantation itself. For estimating purposes, we assume that these divergences between costs and charges largely cancel each other out, but that the net effect is that actual costs are about 20 percent less than the Milliman charge estimates.

In analyzing the medical costs of the rule, we first estimate the costs per transplant of the three most common organ transplants: Kidneys, livers, and hearts. Between them, they account for about 90 percent of all transplants. Kidneys alone are over 60 percent of all organs transplanted.

TABLE 6—FIRST YEAR COST PER HEART TRANSPLANT ($)

Heart	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (6 months)	Net transplant cost
30 days pre-transplant	43,000	9,000	20,000	0	14,000
Procurement	102,000	0	0	0	102,000
Hospital Transplant Admission	887,000	177,000	0	0	710,000
Physician During Admission	92,000	18,000	0	0	74,000
180 Days Medical Post Discharge	223,000	45,000	60,000	0	118,000
180 Days Drugs Post Discharge	34,000	7,000	10,000	15,000	32,000
Total	1,381,000	256,000	90,000	15,000	1,050,000

As shown in Table 6, the one-time cost of a heart transplant is just over one million dollars after adjusting charges to costs and reducing the estimates to account for medical and drug costs, both pre- and post-discharge, that are unlikely to be transplant-related.

TABLE 7—FIRST YEAR COST PER LIVER TRANSPLANT ($)

Liver	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (6 months)	Net transplant cost
30 days pre-transplant	41,000	8,000	10,000	0	23,000
Procurement	94,000	0	0	0	94,000
Hospital Transplant Admission	463,000	93,000	0	0	370,000
Physician During Admission	56,000	11,000	0	0	45,000
180 Days Medical Post Discharge	127,000	25,000	60,000	0	42,000
180 Days Drugs Post Discharge	31,000	6,000	10,000	15,000	30,000

[34] T. Scott Bentley and Steven J. Phillips, 2017, available to download at *http://www.milliman.com/insight/2017/2017-U_S_-organ-and-tissue-transplant-cost-estimates-and-discussion/.*

TABLE 7—FIRST YEAR COST PER LIVER TRANSPLANT ($)—Continued

Liver	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (6 months)	Net transplant cost
Total	812,000	143,000	80,000	15,000	604,000

Table 7 shows the estimated average cost for a liver transplant, estimated on the same basis as heart transplants. Table 8 estimates kidney transplant costs, with an additional adjustment. In the case of a kidney transplant, there is an off-setting saving for the elimination of ESRD kidney dialysis costs. This is a substantial saving and in the first year alone, saves about one-third of the estimated transplant cost.

TABLE 8—FIRST YEAR COST PER KIDNEY TRANSPLANT ($)

Kidney	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (6 months)	Net transplant cost subtotal	Annual dialysis costs avoided	Net first year cost
30 days pre-transplant	30,000	(6,000)	(10,000)	0	14,000	0	14,000
Procurement	97,000	0	0	0	97,000	0	97,000
Hospital Transplant Admission	159,000	(32,000)	0	0	127,000	0	127,000
Physician During Admission	25,000	(5,000)	0	0	20,000	0	20,000
180 Days Medical Post Discharge	75,000	(15,000)	(60,000)	0	0	* (90,000)	(90,000)
180 Days Drugs Post Discharge	29,000	(6,000)	(10,000)	15,000	28,000	0	28,000
Total	415,000	(64,000)	(80,000)	15,000	286,000	(90,000)	196,000

* Estimated annual dialysis costs.

Using these results, it is possible to estimate the extended effects of added and reduced costs over time. In Table 9, we provide a 5-year projection, giving both results for a patient who survives all 5 years with the transplanted organ, and the same estimate adjusted to assume only an 80 to 90 percent patient and organ survival rate for the full 5 years (the higher rate is for kidneys). These estimates do not account for all the varied circumstances that can arise, such as patients whose organs fail and who are then re-transplanted. They include the costs of immunosuppressive drugs. In the case of kidney transplants, the estimates assume a savings of $90,000 for ending dialysis, offset by a $30,000 cost for the immunosuppressive drugs. The weighted results take into account that kidneys account for about 65 percent of transplants for these three organs. As shown in the table, kidney transplants actually reduce costs for the patients who survive the full 5-year period.

TABLE 9—FIVE YEAR COSTS PER WEIGHTED AVERAGE TRANSPLANT ($)

Annual Percent of Total TX	Heart	Liver	Kidney	All three organs weighted
	11%	24%	65%	100%
First Year	1,050,000	604,000	196,000	387,860
Second Year	20,000	20,000	(60,000)	(32,000)
Third Year	20,000	20,000	(60,000)	(32,000)
Fourth Year	20,000	20,000	(60,000)	(32,000)
Fifth Year	20,000	20,000	(60,000)	(32,000)
Total	1,130,000	684,000	(44,000)	259,860
80 to 90% Survival Total *	1,122,000	676,000	(20,000)	272,660

* Rate is higher for kidneys than for other organs. All deaths are assumed to occur prior to Year 2 (that is, before any dialysis-related savings can accrue).

An annually growing performance increase to about 8,000 additional transplants in the last year of the next 4-year OPO performance period is essential in order to meet the HHS' 2030 goal of doubling the number of kidneys available for transplants. As Table 10 shows, this will require multi-billion dollar increases over current transplant spending levels by the middle of this decade (and far more by 2030). As we show in our benefit estimates, these levels are exceeded by the life-saving and life-extending benefits of these additional transplants. As discussed later in this analysis, most of the cost increases we estimate in this rule are reimbursed by private payers, rather than by Medicare.

HHS has set a quantitative goal of doubling the number of kidneys available for transplant by 2030. While there are multiple pathways to achieve this goal, the main approach for achieving this ambitious goal is to increase the number of deceased donors. This will require continuous improvements over time, and we have estimated the approximate numbers that would have to be achieved in the next five years to move about half way towards an annual increase of approximately 16,000 more kidney

transplants by 2030, as shown in Table 10.

In Tables 10 and 13, we show hypothetical projections for annual results for costs and benefits, respectively, as each cohort of new transplants arrives over the OPO performance period from 2021 to 2025—assuming that both donor and transplant rates improve by an average of 20 percent or to the top 25 percent level, whichever is higher, similar to the highest growth rates show in Tables 4 and 5 and using the estimate of 7,283 transplants shown in Table 5. As previously discussed, these are optimistic rates that assume a wide variation in improvements, including improvements by many OPOs in the top 25 percent as well as in the lower performers. These estimates include totals for all organs since one deceased donor normally provides multiple organs. The 7,000 increase shown for 2025 includes about 4,500 kidneys transplanted. These figures assume a 5-year patient and graft survival rate of 90 percent for kidney transplants. As can be seen, the costs grow substantially with each new cohort. These tables include an extra column that shows the effects of this 5-year cohort in the sixth and future years. While total costs grow over time with each new and larger cohort of new transplants, the savings from reduced kidney dialysis costs from previous kidney transplants grow over time, as do the benefits for those patients whose lives were both extended and improved by transplantation.

TABLE 10—HIGHER COSTS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE TO REACH HIGHER OF 20% OR TOP 25% ($ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer term effect from 2021–2025 cohorts
Increase over base year in number of transplants (20% annual increments)	1,434	2,868	4,301	5,735	7,169	
Costs for 2021–2 Cohort	$556	($39)	($39)	($39)	($39)	($39)
Costs for 2022–3 Cohort		1,112	(78)	(78)	(78)	(78)
Costs for 2023–4 Cohort			1,668	(117)	(117)	(117)
Costs for 2024–5 Cohort				2,224	(156)	(156)
Costs for 2025–6 Cohort					2,781	(195)
Total	556	1,073	1,551	1,990	2,391	(585)

Pancreas research projects do count in our performance measures, as explained earlier in the preamble. However, we do not include pancreatic research in our estimates of either costs or benefits since we have no basis for estimating either under current reporting. Experimental or other research procedures that involve transplantation of islets from an organ donor into a person on the waiting list for a pancreas are counted as transplants and included in our cost and benefit estimates, but the research projects displayed in Table 5 and excluded from Tables 10 to 15 are those specifically categorized under the OPTN's reporting instructions as research not involving a transplant. In 2016 to 2018 the number of such pancreas research projects have been between 500 and 600 a year (579 in 2018). This is 1.73 percent of the number of transplants in 2018, and we project a similar fraction in our estimates for future years. Only bona fide research conducted by a qualified researcher using a pancreas from an organ donor would be counted, and it would be counted as a single research project regardless of the number of research activities performed using that one pancreas and its islets. It is also conceivable that a pancreas might be used for research when it would otherwise have been used for a transplant. We do not have data to quantify how frequently this may occur and have no basis for subtracting either lives lost or transplant cost savings from any such cases in our estimates of benefits and costs. In addition, any such use would likely raise issues of ethics, payment, and donor family consent. Regardless, we anticipate focusing on pancreatic research performance in both our payment and performance review functions to prevent abuse.

We note that the expenditure data include procurement costs, which average almost $100,000 per organ transplanted across all three organ types. Accordingly, a cohort of 1,000 patients would involve total procurement costs of about $100 million, and a cohort of 8,000 patients about $800 million. These data do not include all organ types, nor all cost savings (notably end-of-life costs), but are a reasonable approximation to the magnitudes involved. The procurement costs are paid to OPOs by transplant centers and finance the costs associated with the actual donation and transportation of the organ to the transplant program as well as the general operations of the OPO. These costs are, as discussed later in this analysis, largely reimbursed by health insurance.

Our estimates also do not include costs of changes or advances in treatment options for both liver and heart patients, such as new drug treatments for hepatitis C, one of the main causes of liver failure, or heart assist devices that can serve as a bridge while waiting for a heart transplant.

In Table 11, we provide lower cost estimates using the same per-transplant inputs but with aggregates reflecting only the minimum number of new annual transplants required to reach the top 25 percent. As in Table 10, these estimates reflect the timeline changes in the final rule and the need for OPOs to begin immediately to make the reforms needed to raise their performance. As is in Table 10, we exclude pancreas research from our projection. These are hypothetical costs assuming that every OPO could predict future success rates precisely and that all OPOs would act to achieve only the exact minimum level needed to avoid decertification. Compliance starts in 2021 to meet the timelines of this final rule.

TABLE 11—HIGHER COSTS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE TO REACH HIGHER OF 20% OR TOP 25% ($ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer term effect from 2021–2025 cohorts
Increase over base year in number of transplants (20% annual increments)	180	360	539	719	899	
Costs for 2021–2 Cohort	$70	($5)	($5)	($5)	($5)	($5)
Costs for 2022–3 Cohort		139	(10)	(10)	(10)	(10)
Costs for 2023–4 Cohort			209	(15)	(15)	(15)
Costs for 2024–5 Cohort				279	(20)	(20)
Costs for 2025–6 Cohort					349	(24)
Total	70	135	195	250	300	(73)

In Table 12, we describe an intermediate scenario where all lower-performing OPOs (Tiers 2 and 3) achieve the top 25 percent threshold rate (but no more) for organs used in transplantation and the OPOs already in Tier 1 do not improve their performance. For the ease of analysis, both the lowest and intermediate scenarios assume that OPOs could predict their performance so as to achieve exactly the right level to avoid any decertification penalty. These scenarios illustrate that there are a range of outcomes that we are unable to predict with any precision since they will depend on OPO by OPO management and other decisions.

TABLE 12—INTERMEDIATE COSTS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE TO REACH TOP 25% ($ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer term effect from 2021–2025 cohorts
Increase over base year in number of transplants (20% annual increments)	486	972	1,457	1,943	2,429	
Costs for 2021–2 Cohort	$188	($13)	($13)	($13)	($13)	($13)
Costs for 2022–3 Cohort		377	(26)	(26)	(26)	(26)
Costs for 2023–4 Cohort			565	(40)	(40)	(40)
Costs for 2024–5 Cohort				754	(53)	(53)
Costs for 2025–6 Cohort					942	(66)
Total	188	364	526	674	810	(198)

2. *Effects on Patients.* On average, organ transplants significantly extend lives. There is extensive literature on life expectancy before and after transplant, quality of life, and cost savings for kidney transplant patients. A recent literature synthesis found essentially universal agreement that kidney transplants were not only substantially life extending, but also cost reducing.[35] The authors performed an extensive literature search and found that from 1968 to 2007, seventeen studies assessed the cost-effectiveness of renal transplantation. The authors concluded that ''[r]enal transplantation . . . is the most beneficial treatment option for patients with end-stage renal disease and is highly cost-effective compared to no therapy. In comparison to dialysis, renal transplantation has been found to reduce costs by nontrivial amounts while improving health both in terms of the number of years of life and the quality of those years of life'' (page 31). More recent studies and other syntheses have reached similar conclusions. For example, in the article, ''Systematic Review: Kidney Transplantation Compared with Dialysis in Clinically Relevant Outcome,'' the authors reviewed 110 studies and concluded that the vast majority of kidney transplant recipients showed major improvement in life quality and reductions in mortality compared to those remaining on dialysis.[36] The *Annual Data Report* of the United States Renal Data System utilizes national data on ESRD, and reports that deaths per 1,000 patient years in 2016 were about 134 for dialysis patients but only about 29 for transplant recipients.[37] There are similar data on other organs. For example, in the RIA published in the 1998 final rule establishing the governance procedures for the OPTN (63 FR 16296), HHS estimated that ''the annual benefits of organ transplantation include about eleven thousand lives vastly improved by kidney transplantation, and another eight thousand lives both vastly improved and prolonged by transplantation of other major organs'' (63 FR 16323).

Accordingly, the per-patient potential benefits are substantial. For each new kidney transplant, there would be an average of 10 additional life years per transplant patient compared to those on dialysis.[38] Using the more usual metric of survival rates, the 5-year survival rate for kidney transplant patients is 86 percent (Milliman, page 13).

HHS ''Guidelines for Regulatory Impact Analysis'' explain the concept of Quality-adjusted life years (QALYs).[39] QALYs enable estimates of the value that people are willing to pay for life-prolonging and life-improving health care interventions of any kind (see sections 3.2 and 3.3 of the HHS Guidelines for a detailed explanation). The QALY amounts used in any estimate of overall benefits, including this one, are not meant to be precise estimates, but instead are rough statistical measures that allow an overall estimate of benefits expressed in dollars (usually by multiplying QALYs by a

[35] Huang, E, et al., ''The Cost-Effectiveness of Renal Transplantation,'' *When Altruism Isn't Enough,* edited by Sally Satel (AEI Press, 2008).

[36] Tonelli M, et al., *Am J Transplant* 2011: 2093–2109.

[37] USRDS 2018 Annual Data Report report, volume 2, Figure 5.1; accessed at *https://www.usrds.org/adr.aspx* and *https://www.usrds.org/2018/download/v2_c05_Mortality_18_usrds.pdf*).

[38] Wolfe RA et al., ''Comparisons of Mortality in All Patients on Dialysis, Patients on Dialysis Awaiting Transplantation, and Recipients of a First Cadaveric Transplant,'' *NEJM,* 1999, 341:1725–30; accessed at *http://www.nejm.org/doi/full/10.1056/NEJM199912023412303#t=article*).

[39] *https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis.*

dollar estimate of the value of a statistical life year).[40]

Table 13 provides estimates of the life-extending and life-improving value of the rule assuming that it succeeds in improving OPO performance in early years at the magnitudes necessary to meet the 2030 HHS goal (to do so we model achieving the 75th percentile, or a 20 increase, whichever is higher, as shown in Table 5). The increase of 7,283 transplants in Table 13 is taken from Table 5. For simplicity, we estimate that transplants occur halfway through the year.

TABLE 13—HIGHER BENEFITS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE TO REACH HIGHER OF 20% OR TOP 25% ($ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer term effect from 2021–2025 cohorts
Increase over base year in number of transplants (20% annual increments)	1,434	2,868	4,301	5,735	7,169	
Benefits for 2021–2 Cohort	$134	$268	$268	$268	$268	$268
Benefits for 2022–3 Cohort		268	537	537	537	537
Benefits for 2023–4 Cohort			403	805	805	805
Benefits for 2024–5 Cohort				537	1,073	1,073
Benefits for 2025–6 Cohort					671	1,342
Total	134	537	1,208	2,147	3,355	4,025

Table 13 shows only the first 5 years of increasing transplants, with an extra year added with no new cohort to illustrate how the benefits for each group grow over time. Over a 10-year period, total life extending benefits from about 18,000 additional kidney transplants would be $23 billion (without discounting) from the five cohorts of additional transplants shown in Table 13 (28,000 organs × 65 percent of which are kidneys × ⅔ patient survival rate × $1 million per surviving transplant recipient in life extending benefits = $23 billion). A similar calculation for all additional transplant recipients reaches a total of $35 billion over 10 years, with even more years of benefits to most of the same recipients yet to come.[41]

We note that these estimates are averages across patients who vary widely in age, medical condition, and life expectancy, as well as type of organ failure. For example, the sickest patients typically have very low life expectancies without transplant so they stand to gain the most years of life from a transplant. However, these same patients, on average, have slightly lower survival rates post-transplant. Organ and patient survival issues are complex and dealt with by detailed policies and procedures developed and used by the transplant community. These policies are reviewed and revised frequently based on actual experience and changing technology—over time, the success rate from using marginal organs and in transplanting older and sicker patients have both increased substantially. There are additional complexities that we have not used in these broad estimates, such as the ability of kidney transplant recipients to return to dialysis if a transplanted kidney fails, leading to both additional costs and additional benefits. For presentation purposes, we have not discounted future costs and benefits to ''present value'' in the preceding tables, but handle discounting in our annualized estimates shown in the Accounting Table that follows. For purposes of this analysis, the proper measure is the average gain across all patients who would receive transplants in the presence of the rule but not in its absence.

Table 14 shows estimates using the same per-transplant life-saving benefits but with aggregates reflecting the lower figure of 1899 new annual transplants shown in Table 5 as an estimate of those number of transplanted need to meet the median threshold rates to avoid de-certification based on the outcome measures. These are hypothetical benefits assuming that every OPO could predict future success rates precisely and that all OPOs would be able to act to achieve only the exact minimum level needed to avoid automatic decertification.

TABLE 14—LOWER BENEFITS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE ONLY TO REACH MEDIAN ($ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer Term Effect from 2021–2025 Cohorts
Increase over base year in number of transplants (20% annual increments)	180	360	539	719	899	
Benefits for 2021–2 Cohort	$17	$34	$34	$34	$34	$34
Benefits for 2022–3 Cohort		34	67	67	67	67
Benefits for 2023–4 Cohort			50	101	101	101
Benefits for 2024–5 Cohort				67	135	135
Benefits for 2025–6 Cohort					84	168
Total	17	67	151	269	421	505

[40] Using such a measure to make coverage or reimbursement determinations is prohibited by Section 1182(e) of the Act. That prohibition does not apply to the situation addressed in this proposed rule, where the purpose is not to determine medical coverage for individual patients, but to measure overall success in raising the number of persons who obtain life-saving treatments.

[41] This method of calculating the value of kidney transplantation is similar to but substantially simplified from the method used in P.J. Held et al., ''A Cost-Benefit Analysis of Government Compensation of Kidney Donors,'' American Journal of Transplantation, 2016, pages 877–885 (plus 65 pages of supplementary details explaining all assumptions, data sources, and calculations). Factors for Hearts and Livers come from Elisa F. Long et al., ''Comparative Survival and Cost-Effectiveness of Advance Therapies for End-Stage Heart Failure,'' *http://circheartfailiure.ahajournals.org*, April 7, 2017; and Fredrik Aberg et al., ''Cost of a Quality-Adjusted Life Year in Liver Transplantation: The Influence of the Indication and the Model for End-Stage Liver Disease Score,'' Liver Transplantation 17:1333–1343, 2011.

Finally, we have estimates of benefits that correspond to the number of organ transplants needed for all OPOs to reach the level of the Top 25 percent of all OPOs. As shown in Tables 5 and 12, using 2018 data we estimate that 2,429 additional transplants would be needed to reach that level. As is the case for our other estimates, this is a hypothetical level that in this case corresponds to an Intermediate level of performance. In the real world, it would be unlikely that an OPO would achieve that exact level of performance, and best practice suggests a more prudent approach would be to strive for a higher level if for no other reason than to avoid some unexpected shortfall. (As before, we estimate no QALY value for research projects that use pancreata, and have no basis for valuing research that does not include an actual transplant.)

TABLE 15—INTERMEDIATE BENEFITS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE ONLY TO REACH MEDIAN ($ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer term effect from 2021–2025 Cohorts
Increase over base year in number of transplants (20% annual increments)	486	972	1,457	1,943	2,429	
Benefits for 2021–2 Cohort	$45	$91	$91	$91	$91	$91
Benefits for 2022–3 Cohort		91	182	182	182	182
Benefits for 2023–4 Cohort			136	273	273	273
Benefits for 2024–5 Cohort				182	364	364
Benefits for 2025–6 Cohort					227	455
Total	45	182	409	727	1,137	1,364

3. *Implementation and Continuing Costs.* The requirements of this final rule would necessarily have to be read, understood, and implemented by all OPOs. This would create one-time as well as continuing costs. In some cases, these costs would be low, involving understanding the new outcome measures and learning where the OPO stands in relationship to other OPOs in meeting the new outcome measures. In other cases, the OPO may need to significantly change its practices and techniques, increase frontline staffing, and/or change senior leadership.

In all cases, time will have to be spent deciding whether and how to change existing policy and procedures. These effects would be on primarily the 58 OPOs, but secondarily the approximately 750 transplant programs in about 250 transplant hospitals and to a lesser extent the 6,000 donor hospitals. Ultimately, as OPO performance increases, donor hospitals may have more training activities, participate in more organ donation awareness activities, and have increased operating room or ICU activities associated with increased donations. Transplant programs similarly would need to perform more transplants if OPOs improve their performance. Most of the OPO costs are included in the acquisition costs associated with organ procurement and would be paid by Medicare and other health insurers, including the costs that management will incur in learning these new rules. Therefore, our estimates assume that ongoing management operations will continue at current levels and focus on costs needed to understand the new rules and plan changes needed for compliance, such as QAPI and ECE. We did not receive comments on our estimates as to skills and occupations involved or time likely to be spent.

In total, there are about 400 potentially and directly affected entities or programs. For transplant hospitals (whose business levels will be indirectly affected), we assume that on average there would be 1 hour of time spent by a lawyer, 2 hours of time by an administrator or health services manager, and two hours of time by other staff (we assume registered nurses or equivalent in wage costs) of each affected provider to understand the regulatory change(s) and make the appropriate changes in procedures. We further assume that for one-tenth of these providers, 2 hours of physician time would be needed to consider changes in facility policy. Average hourly costs for these professions, with wage rates doubled to account for fringe benefits and overhead costs, are $139 for lawyers (occupation code 23–1011), $109 for medical and health services managers (occupation code 11–9111), $89 for statisticians (occupation code 15–2041), $73 for registered nurses (occupation code 29–1141), $56 for healthcare social worker (21–1022), and $203 for physicians (occupation code 29–1060). The medical and health services managers would include such occupations as transplant administrator, organ procurement coordinator, and director of nursing. The statistician might instead be a computer analyst or operations research analyst at a similar wage. The underlying wage numbers are from BLS statistics for 2018.[42]

We assume that on average, an OPO would involve one person in each occupation listed in the preceding paragraph, and an average of 8 hours on an interdisciplinary team tasked with learning the new rules, understanding their implications for that OPO, and initiating plans to address performance levels as well as to deal with QAPI and ECE issues. Total costs, on average, would be $139 plus $109 plus $89 plus $73 plus $56 plus $203, for a total of $669 per hour and $5,352 (8 × $669) for eight hours. For the 58 OPOs, the first-year cost would therefore be about $310,000 (58 × $5,352).

We also assume that some large fraction of OPOs would either voluntarily, or through decertification and takeover, have a new CEO and perhaps other senior managers, or a new Board of Directors, or both (or, in some cases, the takeover would simply involve an existing Board of Directors assuming an additional DSA responsibility). These costs could involve search costs, potentially higher salary costs for the replacement managers, and legal costs in the cases where the corporation is replaced or merged with the certified OPO newly placed in charge. The extent and magnitude of these types of cost are difficult to predict, as are the numbers of affected OPOs. The costs may be lower, for example, if the low-performing OPO concludes that it cannot meet the new requirements under current management, and voluntarily seeks a merger with another OPO or implements management reforms that do not raise long-term costs. Because we cannot predict the mix of these kinds of alternatives, we assume that these governance and top management-related costs will be $100,000 a year on average for the

[42] *https://www.bls.gov/oes/2018/may/oes_nat.htm.*

bottom-performing half of all OPOs, for a total cost over a 5-year period of $14.5 million (29 × $100,000 × 5).

We also assume that regardless of the precise reform or takeover option involved in a particular DSA, both outgoing and incoming management would undertake careful measures to maintain the integrity and performance of ongoing organ procurement and placement functions with minimal or no disruption. While the analogy is imperfect, and while staff morale problems are common in hospital merger situations, we are unaware of any evidence that patient care was substantially affected adversely by hospital mergers.[43] Accordingly, we assume no major or continuing disruption in the provision of actual services related to organ donation or placement during such transitions.

There would also be continuing and far larger costs over time as OPOs and hospitals manage the substantial increases in numbers of donors and number of organs transplanted, while increasing and improving OPO management of current activities, improved procurement and placement techniques, QAPI, and ECE requests if needed. These procurement costs (including reimbursable overhead activities) are included in the cost estimates in Tables 6 to 8, and average approximately $100,000 per organ. Each additional 1,000 organs would cost about $100 million, with insurance reimbursement and patient cost-sharing covering essentially all of those costs (see the next section of the analysis). As organ procurement grows, there are two significant effects. First, there are economies of scale as OPOs and hospitals expand their donor-related and transplant services. Second, there are substantial volume increases over time that require additional efforts. For each OPO these are potentially multi-million dollar annual cost (and revenue) increases that reflect additional work performed and donation and transplant increases achieved. For both cost savings and cost increases, effects are primarily from staffing changes; we assume there are relatively few fixed investments beyond rent and equipment. And in both cases, current reimbursement policies and programs pay for all reasonable costs. We received no comments on these and other workload, cost, and revenue issues and estimates and have left them only moderately changed.

We do not expect substantial costs would be incurred by CMS. The data collection required for enforcement of the standards already exists and can readily be used to assess performance. OPOs are already reviewed and surveyed on a continuing basis. There would be additional costs for technical assistance, processing ECE requests, and reviewing QAPIs, as well as actions regarding any OPOs with major compliance problems. We anticipate increased appeals related activities, however our expectation is that these would be managed through any necessary reallocations of staff time from lower priority activities. The number of affected facilities is also small compared to the number of facilities that CMS works with on a regular basis. CMS estimates that these oversight activities are unlikely to require more than three or four additional person-years of effort, with annual costs of one million dollars or less.

The preceding analysis does not reflect the potentially substantial transition costs associated with the potentially disruptive to top management process of decertification. However, as previously discussed we believe that these costs will fall almost entirely on the very highest levels of OPO governance, not on the ongoing processes of the OPO in procuring organs or arranging transplant placement performed by professional staff.

E. Effects on Medicare, Medicaid, and Private Payers

The preceding cost estimates include all procurement and transplantation costs, regardless of payer. In practice, however, most of the costs are covered by insurance, and the remainder primarily by patients. Typical insurance shares, both public and private, range from 100 percent (Medicaid) to 80–90 percent in private insurance and Medicare, taking into account hospital, physician, ESRD, and drug costs. While overall cost sharing by category of expense is broadly similar among insurance sources and across organ types, both the transplant cost and the shares paid by public and private insurance vary widely by organ type. Specifically, for heart and liver transplants, the vast majority of patients are enrolled in private insurance or in some cases in Medicaid because of the age restrictions of Medicare (unless disabled). According to the OPTN, in 2018 only 19 percent of heart transplants and 22 percent of liver transplants were performed in recipients 65 and older. In contrast, the vast majority of kidney transplants (about 80 percent) are received by patients who have end-stage renal disease and, as ESRD patients, nearly all are entitled to Medicare regardless of age (about half of ESRD patients are also enrolled in Medicaid, but Medicare is ''primary'' and pays most costs). This ESRD/kidney transplant group also differs radically in initial transplant cost (much lower than for hearts and livers, as shown in Tables 6 through 8), and in cost over time. For kidney transplant recipients who live 4 years or more after the transplant year, total medical costs over time are lower than for dialysis, resulting in savings to Medicare (see Table 8). For ESRD patients who receive kidney transplants, the public insurance programs would likely save money over time.

We do not have a definitive estimate of costs to each category of payer because those shares will change considerably over time as new cohorts of patients are served, and will also change depending on whether costs are estimated for 1, 5, or 10 years or beyond. For kidney transplant recipients, who account for almost two-thirds of transplants, Medicare cumulatively saves more money than the transplant cost by the fourth or fifth year after transplant. One simple calculation method is to consider the weighted average of costs billed to Medicare for each 1,000 patients transplanted and surviving 5 years. Taking into account all the preceding factors, the weighted average total cost billed by providers to all payers would be about $270 million (see Table 9). The Medicare share of that would be about $40 million, largely reflecting the lower initial costs of kidney transplants, the continuing dialysis savings, and the relatively small share of heart and liver transplants paid by Medicare. In the first year for these same 1,000 patients (the year of the actual transplant) the Medicare cost would be about $150 million of the $388 million total, reflecting the Medicare coverage of the majority of transplants as well as the lower average cost for those kidney transplants. Across the first 5 years after the final rule takes effect (years in which much of the dialysis savings are not yet realized), total costs shown in Table 10 over this period are about $10 billion and the average billed to Medicare would be about 25 percent of this, or $2.5 billion.

[43] See Vivian Ho and Barton Hamilton, ''Hospital mergers and acquisitions: does market consolidation harm patients?,'' Journal of Health Economics, September 2000, at *https://www.sciencedirect.com/science/article/abs/pii/S0167629600000527*, and Tim Attebery, A Study to Examine the Relationship Between Hospital Mergers and Patient Experience, Ph.D. Dissertation, University of Alabama, 2018, at *https://search.proquest.com/openview/4653015278eba7781f781fbf0fcbc6c8/1?pq-origsite=gscholar&cbl=18750&diss=y*.

Of this, patients would pay on average almost 20 percent, reducing the Medicare costs to about $2 billion over the 5-year period. Alternatively, if costs only increase by the minimum needed to achieve required standards, total costs and the Medicare share might be only about one fourth as much (see Tables 11 and 12).

F. Effects on Small Entities, Effects on Small Rural Hospitals, Unfunded Mandates, and Federalism

1. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most health care providers regulated by CMS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year, varying by type of provider and highest for hospitals). On average, the 58 OPOs have annual revenues of about $50 million in a market with annual organ acquisition revenues of about $3 billion annually.[44] While few of these would meet SBA revenue size standards for ''small,'' all are, by law, non-profits. Accordingly, almost all of the direct effects on businesses that this rule would create will affect small entities.[45]

The RFA requires that a Regulatory Flexibility Analysis be prepared if a proposed and subsequent final rule would have a ''significant economic impact'' on a ''substantial number'' of such entities. The HHS standard for ''significant economic impact'' is 3 percent or more of annual revenues. Although the HHS position is that this only applies to negative impacts because the RFA requires agencies to ''minimize'' economic impact, HHS practice in cases involving significant positive effects is to perform the analysis, regardless of the statutory issue. In the case of this rule, we expect most OPOs to prosper as they reform their practices to meet the new standards, but some may lose their certification and be replaced by existing, high performing OPOs. The HHS standard for ''substantial number'' is 5 percent or more of those that will be significantly impacted, but never fewer than 20. While there are only 8 OPOs that fall into Tier 3 and we expect that all or most of these will meet our outcome measures within 4 years, there is a possibility that a larger number would not have their agreements renewed because of loss in the competition phase. Hence, we are unable to certify that a Final Regulatory Flexibility Analysis is not required under the RFA. Accordingly, we prepared both Initial and Final Regulatory Flexibility Analyses and this RIA, together with the other preamble sections, meets the requirements for RFAs.

The question arises as to whether transplant programs are affected entities. We believe they are not. They are all medical units within hospitals. Only the hospital itself can be a small entity, and many are, as a consequence of their non-profit status. However, nothing in this rule directly regulates either hospitals or their transplant programs. Moreover, nothing in this rule would have any adverse effects on those programs. They would, instead, likely gain revenues from increases in patients transplanted. The pattern of such increases is impossible to predict since organs are increasingly shared across OPO service area boundaries and, in many cases, across hundreds or thousands of miles. Regardless, in the aggregate, hospital revenues nationwide exceed 1 trillion dollars a year; the estimated costs of this rule assuming higher rather than lower levels of performance over the first 5 years are about $10 billion, averaging $2 billion a year, of which only half falls on transplant programs. This would be a fraction of 1 percent of hospital costs or revenues in the hospitals that host transplant programs, which are generally larger hospitals. Since organ acquisition costs are reimbursed by patient health insurance, net costs to hospitals with transplant programs are approximately zero and may actually be negative.[46] Indeed, if any hospital determined that its transplant program was no longer a profit center, it could simply cease providing that service. Hence, we conclude that there would be no ''significant economic effect'' on a ''substantial number'' of hospitals, and that increases in transplant volume will be neutral or positive.

The potential economic effects on OPOs depend on their ability to meet the thresholds established at the beginning of the 4-year performance period. OPOs who are in Tier 1 should experience positive impacts (a likely increase in organ donors and organ transplants that we estimate to likely be near 20 percent), with revenues from Medicare that reimburses reasonable kidney acquisition costs) and reimbursement from other health insurers. Those OPOs currently at Tier 3 that can achieve the threshold rates over the 4-year period may also benefit from the increased revenue associated with procuring more organs. For OPOs that cannot meet the new outcome measures or improve sufficiently to win the competition for their open DSA, they would incur costs to make the necessary changes to avert a loss of certification. Our final rule methodology is designed to allow all OPOs the opportunity to achieve the threshold rates; however, based on Tables 4 and 5, we believe that there are a range of potential outcomes, assuming high performers remain at steady state or substantially improve over time. Based on 2018 data, these potential outcomes include:

- Eight OPOs in Tier 3 would be subject to de-certification or loss of DSA because they would need to increase their donation and/or transplantation rates by more than 50 percent to meet the Tier 1 threshold rates. These eight are at the most serious risk.
- Approximately 12 DSAs that would be subject to potential takeover because their current OPOs would need to increase their donation and/or transplantation rates by more than 10 to 50 percent to meet the Tier 1 threshold rates.
- Approximately 12 DSAs whose current OPOs would need to achieve relatively little improvement but that would be still subject to potential takeover because they would need to increase their donation and/or transplantation rates by 1 to 10 percent to meet the Tier 1 threshold rates.

In most cases of potential loss of certification for a DSA, we would reasonably expect another OPO to take over that service area, retaining the original staff of the OPO that is being taken over, but changing the leadership and many of the organ procurement practices. Conversely, it is also possible that an OPO taking over a new service area would need to increase its staff or

[44] Brigitte Sullivan, Executive Director, NYU Langone Transplant Institute, ''Maximizing Medicare Cost Report Reimbursement,'' 2015, online at *http://organdonationalliance.org/wp-content/uploads/2015/08/ATC_BSullivan_CostReport_062016_S5N0001.pdf.*

[45] We appreciate that some OPOs are hospital-based. For purposes of this analysis, we focus on their OPO functions separately from their other functions.

[46] Patients are not ordinarily accepted on transplant waiting lists if they do not have the insurance or other means to ensure that they can pay not only the hospital and surgical fees, but also for the immunosuppressive drugs that are needed for post-transplant survival.

incur costs related to retraining, or implementation of best practices unfamiliar to the de-certified OPO's staff. We asked for comments on the costs associated with an OPO entering a new DSA after a decertification, including retraining, leadership, relationship building, and implementation of other best practices, but received no comments with which to inform our estimates. As indicated previously in this analysis, we have assumed that disruption costs to OPO organ procurement practices will be mainly related to replacement of Chief Executive Officers and/or Boards and Board members.

Tables 1 to 3 present a list of all affected OPOs and of the gap between their current performance and the final rule standards. These tables use data from 2018 as the baseline year. Based on preliminary 2019 data, which shows substantial overall national improvement in organ transplantations, if the donor potential remained steady in 2019 as it did from 2017 to 2018, these estimates likely overstate the risk for many OPOs (and, by extension, the scope for potential benefits of this rule). These tables show for each OPO what it would have to achieve over a 4-year period to meet the outcome measures. Since the threshold rate using 2019 data would be established prior to the assessment period, each OPO would know from its own workload data and the latest potential donor data exactly where it stands at any point in time over the 4-year re-certification cycle. Since the reasonable and allowed cost of each OPO's increased effort and performance is covered by Medicare for kidney acquisitions, this is not a cost or revenue issue for the OPOs. Instead, our new outcome measures would create a senior leadership and potentially an organizational survival issue. The future of an OPO depends largely on its performance in obtaining donors and on utilization of those organs for transplantation.

Since all OPOs are non-profit organizations and hence ''small entities,'' all of the alternatives and options presented throughout this preamble meet the RFA requirement that effects on these entities be addressed.

Because the measures we have adopted are performance standards, they provide flexibility to the OPOs in meeting the standards. For example, in addition to all the possible internal reforms that an OPO could make, OPOs could merge, or service areas could be merged. These flexibilities are not limited to bilateral agreements and could involve multiple OPOs in partnership with each other or with transplant hospitals. OPO boards could replace the executive leadership and the new leadership could replace ineffective coordinators. They could work to improve working relationships with donor hospitals within their service areas through programs such as the Workplace Partnership for Life. Should cases arise where an OPO is unable to make the necessary changes or is constrained by circumstances beyond its control so that it cannot reach the performance levels of others, CMS can intervene with technical assistance or to facilitate mergers or other changes. The three tier system put in place by this final rule will facilitate OPO decisions on corrective actions calibrated to their performance tier. We believe that every OPO can meet these standards through good faith reforms to improve both donation and organ placement.

The RFA contains a number of requirements for the content of an Initial or Final Regulatory Flexibility Analysis, including a description of the reasons why action is being considered, a statement of the objectives and legal basis for the rule, a description of any reporting or record-keeping requirements of the rule, and a description of any other Federal rules that duplicate, overlap, or conflict with the proposed or final rule (there are none in this case), among others. This RIA and the preamble taken as a whole meet these requirements. We note that the RFA emphasizes the use of performance rather than design standards, which is precisely what we proposed and are putting in place in this final rule.

2. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule's direct effects do not fall on hospitals and there are no small rural hospitals that operate transplant programs. Accordingly, the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

3. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This rule contains no mandates that directly impose spending costs on state, local, or tribal governments, or by the private sector. Some OPOs would likely find that meeting these standards would require additional spending, but others may find that better performance can be achieved at little or no cost. In either case, reimbursement by both public and private payers would cover all reasonably estimated costs.

4. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule would impose no such requirements.

G. Alternatives Considered

Throughout the preamble sections, the proposed rule presented our proposals and sought comments on potential alternatives. We proposed to implement reform measures that (1) establish empirically-based outcome and process performance measures for OPOs, (2) that can be uniformly applied to all OPOs, (3) that would capture the entire pool of potential deceased-donors, (4) that would use transparent, reliable and objective data that would not require entity-specific judgments, (5) that use data that accounts for geographic differences in the number and causes of death, and (6) that use data that are easily captured and tallied on a continuing annual basis.

In choosing the outcomes measures that we proposed and setting the threshold donation and organ transplantation rate at the top 25 percent of rates as the goal to achieve, but not automatically de-certifying OPOs who had at least one outcome measure at or above the median rate, we sought to strike a balance between the goals set forth by HHS and the potential disruption that could happen if only a few OPOs could comply with our standards. We also analyzed three types of alternatives that could be applied to all the OPOs: Changing the denominator, changing the confidence intervals, and changing the threshold rates. For changes to the denominator, we examined the impact of using the CALC measure as the denominator; using the total unadjusted number of

deaths in the DSA as denominator; and using the total population in the DSA as the denominator. For changes to the confidence interval, we examined the impact of changing the confidence interval (CI) to 90 and 99 percent. For changes to the threshold rates, we examined the impact of setting the threshold at an absolute value based on the geometric mean or the median from the year 2016. For the Hawaii OPO, we analyzed one additional alternative to consider: Using the kidney donation and transplantation rates as a measure of success because of the geographical barriers to transporting the other organs for transplantation outside of Hawaii. We sought comments to these alternatives in addition to our proposed outcome measures.

As explained in both preceding and following sections, we made changes in the final rule dealing with all of these issues.

Changes to the Denominator

CALC as the Denominator

As discussed earlier in the preamble, the CALC method proposed by Goldberg et al., has been published in the literature and presented in various forums. It was endorsed by many commenters. This methodology uses the same NCHS database and also uses inpatient deaths to calculate the denominator. The primary difference between the ''cause, age and location'' consistent with donation methodology adopted in this final rule and the originally proposed methodology is that it uses the ICD–10–CM codes to identify deaths that are consistent with donation (that is, inclusion criteria) whereas the original proposal would exclude ICD–10–CM codes that are an absolute contraindication to organ donation (that is, exclusion criteria). The developers of the CALC methodology believe that the ICD–10 codes used in their inclusion criteria captures nearly 99 percent of all deceased donors according to the OPTN: [12]

- I20–I25 (ischemic heart disease);
- I60–I69 (cerebrovascular disease);
- V–1–Y89 (external causes of morbidity and mortality): Blunt trauma, gunshot wound, drug overdose, suicide, drowning, and asphyxiation.

We performed a comparative analysis of the CALC methodology and the originally proposed methodology. There was consistency in the OPOs that were flagged for donation and organ transplantation rates that were below the top 25 percent. Notably, the differences were in the total donor potential (denominator) with CALC method resulting in a donor potential of 101,479 inpatient deaths in 2017, whereas our proposed methodology had 272,105 inpatient deaths. Where there were differences in OPOs being flagged for the donation rates (the CALC method flagged more OPOs), the differences were minor (only a small number of donors per OPO). If all OPOs could increase their donation rates to the threshold rate, under the originally proposed methodology, there would be an additional 1,015 donors (approximately 10.43 percent increase), whereas the CALC methodology would yield an additional 1,223 donors (12.57 percent increase).

For organs transplanted, we estimated that if all flagged OPOs were to increase their organs transplanted to the range of the top 25 percent, then using the proposed methodology, there would be an additional 4,903 organs transplanted (15.24 percent increase); using the CALC methodology, there were would be 5,590 more organs transplanted (17.37 percent increase). Other than the approximately 2 percent increase in donations and organ transplantation, another difference in the methodologies is the difference in how much of an increase each particular OPO would need to increase in organs transplanted. We sought comments on these differences and whether the CALC method is a more precise and/or accurate assessment of OPO performance. Again, the majority of commenters on the CALC option recommended use of CALC.

All Deaths, Age <= 75 as the Denominator

In addition to analyzing the CALC method for the denominator, we also considered using the total number of deaths of people 75 years and younger, regardless of location or cause of death to define the donor potential. Using total number of deaths as the denominator, the donor potential was estimated at 1,376,541 deaths in 2017 of people 75 years and younger (compared with our donor potential of 272,105 inpatient deaths). Despite this large discrepancy in the denominator, we found very similar results for those OPOs being flagged by our methodology versus an approach that uses total deaths. If all OPOs were able to achieve the threshold 25 percent rate using this methodology, we found that it would have 933 additional donors (compared with the 1,105 with our proposed methodology) and 4,851 more organs transplanted, compared with the 4,903 organs from the originally proposed methodology. Similar to the CALC method, where there were differences in the OPOs being flagged for donation rates, the additional donors needed were mostly in the single digits. For the organ transplantation rates, the greatest differences were not in which OPOs were flagged, but rather, it was the differences by OPO in the number of additional organs that needed to be transplanted in order to reach the top 25 percent threshold rate. Few commenters regarded this as a preferred methodology, although like CALC, it would have created an objective and known baseline method of calculating performance.

Total Population, Age <75

A third alternative denominator that we analyzed used the U.S. population from the 2010 census of persons less than 75 years old as the denominator.[47] A population-based approach to re-certifying OPOs was used by the Department until the passage of the OPO Certification Act of 2000, which specifically raised concerns about ''[a]n exclusive reliance on population-based measures of performance that do not account for the potential in the population for organ donation and do not permit consideration of other outcome and process standards that would more accurately reflect the relative capability and performance of each organ procurement organization.'' While we considered this approach, no commenters favored it; and for the preceding and following reasons, we rejected it in favor of the CALC alternative. In the population-based approach, using the original two-tiered performance metric, we would have had 1,699 more organ donors and 7,000 more organs transplanted if all flagged OPOs were able to increase their performance to that of the top 25 percent. This increase does not seem realistic given how significantly it differs from the increases utilizing the CALC and total death analysis. A fundamental requirement to achieve these increases is a sufficient number of deaths that could lead to organ donation. A population based approach does not account for the death requirement and is problematic given variance in DSA mortality rates from 3.39 to 7.11. We also found a pattern where OPOs in the geographic areas with lower mortality rates, such as the Pacific Northwest, the Rocky Mountain area, New England, Los Angeles area, New York City area, and Hawaii, had depressed performance rates under this method, as compared to the OPOs in the areas of the country with the highest

[47] For convenience, we used less than 75 years old rather than 75 and younger because of how the Census data is publicly reported.

rates of deaths consistent with organ donation.[48] Although we stated that we would not consider a measure that is based solely on population size, we sought comments as to whether there are appropriate risk-adjustments that could be used so that a population measure could be reflective of the organ donation potential. We received no such comments and dropped this option from consideration.

Changing the Confidence Interval

In addition to considering other denominator sources, we considered changing the way in which we measured success. One way in which we measure success is in the confidence that our rate is correctly identifying low performers. Our proposed methodology used a 95 percent CI, so we analyzed the effects of both the 90 percent and 99 percent CIs; that is, we increased and decreased our confidence that we appropriately flagged OPOs based on our donation and organ transplantation threshold rates. By changing to a 99 percent CI, 24 OPOs were flagged for donation rates compared with 33 OPOs (95 percent CI); and, 35 OPOs were flagged for organ transplantation rates compared with 36 OPOs being flagged (95 percent CI). When we examined the effects of the 90 percent CI, the differences were even less noticeable: For donation rates, 35 (90 percent CI) versus 33 (95 percent CI) and for transplantation rates, 38 (90 percent CI) versus 36 (95 percent CI). These changes would, however, have put more OPOs at risk for purely statistical reasons. For this reason and absent any favorable comments we retained the 95 percent CI in the final rule.

Changing the Threshold Rates

An alternative way to measure success would be to change the threshold rate by which OPOs are measured. We examined the impact of using a static, absolute threshold rate based on the geometric mean and the median based on data from 2016 for analyzing data from 2017.

We considered use of a static, absolute threshold based on a geometric mean or median as a viable alternative to use instead of the higher relative performance metric that changes each year, but questioned whether this approach could inadvertently incentivize all OPO performances to move towards a static threshold, thus decreasing total donations and transplantations over time. We sought robust public comments that would support or refute these concerns and comments that would list the potential impacts, benefits, or consequences of implementing this approach. We specifically requested that commenters present data, studies, or other analysis to support their recommendations. We also sought comments on ways to incentivize continual improvement of all OPOs, including high performers and low performers. Additionally, we sought comments on ways to ensure that the rates for re-certification continue to be based upon current performance and appropriately reflect potential improvements and changes in technology (such as the development of an implantable, artificial kidney or bioengineered pancreatic islet cells). None of these requests led to public comments advocating such changes. Accordingly, we did not adopt such a measure in the final rule.

There were other alternatives that we chose not to propose. We had previously received comment in response to our RFI that we should consider using the deaths referred from donor hospitals as our donor potential. This approach could rely on the regulatory requirement for hospitals to report imminent deaths to OPOs. We declined to propose this on the basis of concerns regarding its potential for inaccuracy. We stated that this approach would incorrectly place the requirement to report an imminent death solely on the donor hospital, although this is a joint responsibility shared with an OPO. We received no comments in favor of using donor referrals as our denominator, but received a number of comments that hospitals should report directly to CMS or the OPTN the ventilated deaths. The final rule does not make such changes because of the potential burden to donor hospitals, as discussed earlier in the preamble.

Another option suggested by some members of the OPO community and commenters in response to the RFI and in comments to our proposed rule was to use ventilated deaths for donor potential. While we appreciated this suggestion, there are no standardized databases that would allow us to determine the ventilator status of deaths, and we were concerned this approach incorrectly assigns ''potential donor'' status solely based on the fact that the patient is on a ventilator in an ICU. This approach does not consider the role of OPOs in educating donor hospital staff about the range of potential donors, such that resuscitation efforts and inpatient treatment are sufficient and appropriate so that referrals can be made for organ donation, even for older, single-organ donors. Furthermore, asking hospitals to report the ventilator status of inpatient deaths or expecting OPOs to report that status would create an additional burden for all hospitals (not just transplant hospitals or just OPOs) and is inconsistent with one of our many goals in proposing these new performance measures: To reduce the reporting burdens so that resources can go towards increasing organ donation and transplantation. Therefore, we chose not to adopt this source for estimating the ''donor potential'' in our final rule.

Also discussed in the preamble, we recognize that the OPO in Hawaii is at a considerable geographic disadvantage for placement of almost all the organs it could procure. As an alternative, we considered measuring the performance of the Hawaii OPO based solely on its kidney donation and transplantation rates, excluding other organs, because Hawaii has a kidney transplant program, yet has greater geographic barriers associated with transporting the extra-renal organs outside of the DSA. As set forth in section II.B, above, we are finalizing a requirement to measure the performance of the Hawaii OPO based its kidney transplantation rates and its organ donation rate. We did not adopt the kidney donation rate because almost all organ donors are also kidney donors, so the organ donation rate should be an appropriate proxy for the kidney donation rate.

Using solely these measures, we found that the Hawaii OPO would be in the top 25 percent for the kidney transplantation rates and top median for the organ donation rates (but would need only 3 more donors to meet the top 25 percent threshold rate). If we were to use our proposed measure to assess the Hawaii OPO's performance, it would need one additional donor and 38 additional organs transplanted to meet the threshold rate for the top 25 percent of rates. The reason we did not propose this approach for assessing the Hawaii OPO is that we were aware of newer technologies that could significantly reduce the clinical impact of prolonged transport of extra-renal organs and prefer a policy that encourages the innovation and adoption of these types of technologies for the benefit of all potential recipients. We sought comments on this alternative or any other approach that would accurately measure the performance of the Hawaii OPO, such as a phased approach to implementing our new measures. The comments we received generally supported relying on a kidney performance measure alone, and we have adopted that approach in the final

[48] Cannon RM, Jones CM, et al., ''Patterns of geographic variability in mortality and eligible deaths between organ procurement organizations,'' *AmJTransplant.* 2019;00:4 (Fig. 2).

rule. We believe that as technology improves, the Hawaii OPO will have both the life-saving incentive and ability to transport more organs across oceanic distances, but that any specific requirement imposed at this time would risk rapid obsolescence.

In analyzing all these different alternatives, we recognized that there were many OPOs whose performance is in the top 25 percent, regardless of which methodology was used. These OPOs are truly high performers and should be the models for the other OPOs. We encourage those OPOs to continue to strive to be top performers and encourage the widespread uptake of their best practices.

In summary, we welcomed comments both on the comparative advantages and disadvantages of alternatives within the scope of the OPO proposed rule, and suggestions for other alternatives that could be addressed in subsequent rule-makings or administrative actions to further improve performance of the organ donation and transplantation system. We received some suggestions for minor improvements in the standards we proposed many recommendations to adopt both CALC; a suggestion to adopt a system with tiers to identify performance and more graduated options that would recognize major progress towards the standards; numerous comments encouraging competition among OPOs; and comments encouraging us to take action more quickly. These last four and a number of more minor changes have been adopted in this final rule.

H. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 16 we have prepared an accounting statement showing the classification of the benefits, transfers, and costs that we estimate may arise from the reforms under this final rule.

These reforms' effects are likely to be more substantial in out-years than in the nearer term, and the annualized estimates provided in this table display the effects that may be expected over the next 5 years, rather than over a longer period of time. The performance uncertainties, technology uncertainties, and future policy uncertainties are so great that we are reluctant to project further into the future. This means, however, that the Accounting Table estimates do not include substantial out-year benefits to patients, additional savings to the ESRD program, and substantial costs to public and private insurance programs that will occur outside the 5-year estimating window. Also, the effects of this rule on organ recovery and transplantation are of unusual uncertainty even in the short run. The factors influencing both upper and lower bounds for benefit and cost reduction estimates are as discussed previously in this RIA.

The rule generates a cluster of interrelated effects, so we are treating the increase in health care expenditures as ''negative benefits'' for purposes of the Accounting Table.

TABLE 16—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED BENEFITS, TRANSFERS, AND COSTS ($ MILLIONS)

Category	Primary estimate	Low estimate	High estimate	Units		
				Year dollars	Discount rate (%)	Period covered
Benefits:						
Health Benefits Annualized Monetized ($million/year)		<0	1,370	2,017	7	2022–2026
		<0	1,430	2017	3	2022–2026
Medical Expenditure Annualized Monetized ($million/year)		>0	−1,450	2017	7	2022–2026
		>0	−1,450	2017	3	2022–2026
Benefits Notes: Because increased transplant activity imposes costs upfront but yields savings over time, a longer time horizon would show medical expenditure impacts falling in magnitude, potentially (for the portion of the range shown in the ''High Estimate'' column) to the point of being exceeded by longevity benefits.						
Costs:						
Annualized Monetized ($million/year)	10	10	10	2017	7	2022–2026
	10	10	10	2017	3	2022–2026
Cost Notes: Administrative costs in the event of OPO decertification and for regulatory compliance are believed to be relatively minor compared to the high costs and benefits of increasing donors and transplants.						
Transfers	None quantified.					

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule has been designated a significant regulatory action as defined by Executive Order 12866, and is expected to be an E.O. 13771 regulatory action.

J. Conclusion

This rule would substantially reform the incentives facing OPOs and as a result, increase organ procurement and transplants over time for all organs, while reducing continuing costs for dialysis and other treatments for patients with severe kidney disease. Organ transplants are life-saving and life-extending events. Predicting future behavior is particularly difficult when major changes in rewards, penalties, and incentives are created, so all estimates should be regarded as subject to substantial uncertainty.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 486

Definitions, Medicare, Organ procurement.

For the reasons set forth in the preamble, the Centers for Medicare &

Medicaid Services amends 42 CFR chapter IV, part 486 as set forth below:

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 1. The authority citation for part 486 continues to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b–8, and 1395hh.

■ 2. Section 486.302 is amended by adding definitions for ''Assessment period'', ''Death that is consistent with organ donation'', ''Donation rate'', ''Donor potential'', ''Kidney Transplantation rate'', ''Lowest rate among the top 25 percent'', and ''Organ transplantation rate'' to read as follows:

§ 486.302 Definitions.

* * * * *

Assessment period is a 12-month period in which an OPO's outcome measures will be evaluated for performance. The final assessment period is the 12-month assessment period used to calculate outcome measures for re-certification.

* * * * *

Death that is consistent with organ donation means all deaths from the state death certificates with the primary cause of death listed as the ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–1–Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation.

* * * * *

Donation rate is the number of donors as a percentage of the donor potential.

* * * * *

Donor potential is the number of inpatient deaths within the DSA among patients 75 and younger with a primary cause of death that is consistent with organ donation. For OPOs servicing a hospital with a waiver under § 486.308(e), the donor potential of the county for that hospital will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county.

* * * * *

Kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA as a percentage of the donor potential.

* * * * *

Lowest rate among the top 25 percent will be calculated by taking the number of total DSAs in the time period identified for establishing the threshold rate. The total number of DSAs will be multiplied by 0.25 and rounded to the closest integer (0.5 will round to the higher integer). The donation rates and organ transplantation rates in each DSA will be separately ranked and the threshold rate will be the rate that corresponds to that integer when counting down the ranking.

* * * * *

Organ transplantation rate is the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs transplanted into patients on the OPTN waiting list as part of research are included in the organ transplantation rate. The organ transplantation rate will be risk-adjusted for the average age of the donor potential using the following methodology:

(1) The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

(2) Calculate a national age-specific transplantation rate for each age group.

An expected transplantation rate for each OPO is calculated as $\Sigma(g=1)Gdg*Rg/\Sigma gdg$, where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific national transplantation rate in age group g, and Σgdg is the OPO's total number of individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

(3) Calculate the age-adjusted organ transplantation rate as (O/E)*P, where O is the OPO's observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

* * * * *

■ 3. Effective July 31, 2022, § 486.302 is further amended by—

■ a. Revising the definition of ''Donor'';

■ b. Removing the definitions of ''Eligible death'', ''Eligible donor'', ''Expected donation rate'', and ''Observed donation rate'';

■ c. Revising the definition of ''Organ''; and

■ d. Removing the definition of ''Standard criteria donor (SCD)''.

The revisions reads as follows:

§ 486.302 Definitions.

* * * * *

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured and is used for research or islet cell transplantation.

* * * * *

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation.

Organ type	Number of organs transplanted
(1) Right or Left Kidney	1
(2) Right and Left Kidney	2
(3) Double/En-Bloc Kidney	2
(4) Heart	1
(5) Intestine	1
(6) Intestine Segment 1 or Segment 2	1
(7) Intestine Segment 1 and Segment 2	2
(8) Liver	1
(9) Liver Segment 1 or Segment 2	1
(10) Liver Segments 1 and Segment 2	2
(11) Right or Left Lung	1
(12) Right and Left Lung	2
(13) Double/En-bloc Lung	2
(14) Pancreas (transplanted whole, research, islet transplant)	1
(15) Pancreas Segment 1 or Segment 2	1
(16) Pancreas Segment 1 and Segment 2	2

* * * * *

■ 4. Section 486.316 is amended by revising paragraphs (a) through (c) and adding paragraphs (f) and (g) to read as follows:

§ 486.316 Re-certification and competition processes.

(a) *Re-certification of OPOs.* Based upon performance on the outcome measures set forth in § 486.318 and the re-certification survey, each OPO will be designated into either Tier 1, Tier 2, or Tier 3. The tier in which the OPO is designated will determine whether the OPO is re-certified (Tier 1), must compete to retain its DSA (Tier 2), or will receive an initial de-certification determination (Tier 3).

(1) *Tier 1.* An OPO is re-certified for at least an additional 4 years, the OPO's DSA is not opened for competition, and the OPO can compete for any open DSA if it meets all of the following:

(i) It has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360; and

(ii) It meets the outcome requirements as described in § 486.318(e)(4) for the final assessment period of the agreement cycle.

(2) *Tier 2.* An OPO's DSA is open for competition and the OPO is eligible to compete to retain its DSA and for any

open DSA if it meets all of the following:

(i) It has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360; and

(ii) It meets the outcome requirements as described in § 486.318(e)(5) at the final assessment period of the agreement cycle.

(3) *Tier 3.* An OPO will receive a notice of de-certification determination under § 486.314 and cannot compete for any open DSA if it meets either of the following:

(i) Has been shown by survey to not be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360; or

(ii) Has outcome requirements as described in § 486.318(e)(6) at the final assessment period of the agreement cycle.

(b) *De-certification and competition.* If an OPO fails to meet the outcome measures set forth in § 486.318(e)(6) at the final assessment period prior to the end of the agreement cycle, or it meets the requirements described in paragraph (a)(3) of this section:

(1) CMS will send the OPO a notice of its initial de-certification determination and the OPO has the right to appeal as established in § 486.314;

(2) If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs that qualify to compete for open service areas as set forth in paragraph (c) of this section. The de-certified OPO is not permitted to compete for its open area or any other open area.

(3) The OPO competing for the open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(c) *Criteria to compete.* To compete for an open DSA, an OPO must meet the performance requirements of the outcome measures for Tier 1 or Tier 2 at § 486.318(e)(4) and (5), and the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360 at the most recent routine survey. The OPO must compete for the entire DSA.

* * * * *

(f) *Extension of the agreement cycle for extraordinary circumstances.* OPOs can seek a 1-year extension of the agreement cycle if there are extraordinary circumstances beyond the control of the OPOs that has affected the data of the final assessment period so that it does not accurately capture their performance. OPOs must request this extension within 90 days of the end of the occurrence of the extraordinary circumstance but no later than the last day of the final assessment period.

(g) *Exception.* For the 2022 recertification cycle only, an OPO is recertified for an additional 4 years and its service area is not opened for competition when the OPO meets one out of the two outcome measure requirements described in § 486.318(a)(1) and (3) for OPOs not operating exclusively in the noncontiguous States, Commonwealths, Territories, or possessions; or § 486.318(b)(1) and (3) for OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions. An OPO is not required to meet the second outcome measure described in § 486.318(a)(2) or (b)(2) for the 2022 recertification cycle. If an OPO does not meet one of the outcome measures as described in paragraphs § 486.318(a)(1), (a)(3), (b)(1), or (b)(3), or has been shown by survey to not be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, the OPO is de-certified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

■ 4. Section 486.318 is amended by adding paragraphs (a)(4), (b)(4), (c)(3), (d), (e), and (f) to read as follows:

§ 486.318 Condition: Outcome measures.

(a) * * *

(4) The outcome measures described in § 486.318(a)(1) through (3) are effective until July 31, 2022.

(b) * * *

(4) The outcome measures described in § 486.318(b)(1) through (3) are effective until July 31, 2022.

(c) * * *

(3) An OPO's performance on the outcome measures described in § 486.318(a)(1) through (3) and § 486.318(b)(1) through (3) is based on the data described in § 486.318(c)(1) and (2) until July 31, 2022.

(d) An OPO is evaluated by measuring the donation rate and the organ transplantation rate in their DSA.

(1) For all OPOs, except as set forth in paragraph (d)(2) of this section, for all OPOs:

(i) The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

(ii) The organ transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. The organ transplantation rate is adjusted for the average age of the donor potential.

(iii) The numerator for the donation rate is the number of donors in the DSA. The numerator for the organ transplantation rate is the number of organs transplanted from donors in the DSA. The numbers of donors and organs transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11 of this title. For calculating each measure, the data used is from the same time period as the data for the donor potential.

(iv) The denominator for the outcome measures is the donor potential and is based on inpatient deaths within the DSA from patients 75 or younger with a primary cause of death that is consistent with organ donation. The data is obtained from the most recent 12-months data from state death certificates.

(2) For the OPO representing the Hawaii DSA:

(i) The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

(ii) The kidney transplantation rate is calculated as the number of kidneys transplanted from kidney donors in the DSA as a percentage of the donor potential.

(iii) The numerator for the donation rate is the number of donors in the DSA. The numerator for the kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA. The numbers of donors and kidneys transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11 of this title. For calculating each measure, the data used is from the same time period as the data for the donor potential.

(iv) The denominator for the outcome measures is the donor potential and is based on inpatient deaths within the DSA from patients 75 or younger with a primary cause of death that is consistent with organ donation. The data is obtained from the most recent

12-months data from state death certificates.

(e) An OPO must demonstrate a success rate on the outcome measures in accordance with the following parameters and requirements:

(1) For each assessment period, threshold rates will be established based on donation rates during the 12-month period immediately prior to the period being evaluated:

(i) The lowest rate among the top 25 percent in DSAs, and

(ii) The median rate among the DSAs.

(2) For each assessment period, threshold rates will be established based on the organ transplantation or kidney transplantation rates during the 12-month period prior to the period being evaluated:

(i) The lowest rate among the top 25 percent, and

(ii) The median rate among the DSAs.

(3) The 95 percent confidence interval for each DSA's donation and organ transplantation rates will be calculated using a one-sided test.

(4) Tier 1—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the top 25 percent threshold rate established for their DSA will be identified at each assessment period.

(5) Tier 2—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the median threshold rate established for their DSA but is not in Tier 1 as described in paragraph (e)(4) of this section will be identified at each assessment period.

(6) Tier 3—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation or organ transplantation rates that are below the median threshold rate established for their DSA will be identified at each assessment period. OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are below the median threshold rate for their DSA are also included in Tier 3.

(7) For the OPO exclusively serving the DSA that includes the non-contiguous state of Hawaii and surrounding territories, the kidney transplantation rate will be used instead of the organ transplantation rate. The comparative performance and designation to a Tier will be the same as in paragraphs (e)(4), (5), and (6) of this section except kidney transplantation rates will be used.

(f)(1) An OPO's performance on the outcome measures is based on an evaluation at least every 12 months, with the most recent 12 months of data available from the OPTN and state death certificates, beginning January 1 of the first year of the agreement cycle and ending December 31, prior to the end of the agreement cycle.

(2) An assessment period is the most recent 12 months prior to the evaluation of the outcome measures in which data is available.

(3) If an OPO takes over another OPO's DSA on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, we will hold the OPO accountable for its performance on the outcome measures in the new area once 12 months of data are available.

§ 486.328 [Amended]

■ 5. Section 486.328 is amended—

■ a. In paragraph (a) introductory text by removing the word ''Beneficiaries'' and adding in its place the word ''Recipients'' and by removing the acronym ''DHHS'' and adding in its place the acronym ''HHS'';

■ b. By removing and reserving paragraph (a)(4); and

■ c. In paragraph (a)(7), by removing, the word ''eligible''.

■ 6. Section 486.348 is amended by adding paragraph (d) to read as follows:

§ 486.348 Condition: Quality assessment and performance improvement (QAPI).

* * * * *

(d) *Standard: Review of outcome measures.* (1) An OPO must include a process to review its performance on the outcome measure requirements at § 486.318. The process must be a continuous activity to improve performance.

(2) An OPO must incorporate data on the outcome measures into their QAPI program.

(3) If the outcome measure at each assessment period during the re-certification cycle is statistically significantly lower than the top 25 percent of donation rates or organ or kidney transplantation (Tier 2 and Tier 3 OPOs) rates as described in § 486.318(e)(5) and (6), the OPO must identify opportunities for improvement and implement changes that lead to improvement in these measures.

Dated: November 19, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 20, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–26329 Filed 11–24–20; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 85 Wednesday,

No. 232 December 2, 2020

Part V

Department of the Treasury

Internal Revenue Service

26 CFR Parts 1 and 602

Unrelated Business Taxable Income Separately Computed for Each Trade or Business; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9933]

RIN 1545–BO79

Unrelated Business Taxable Income Separately Computed for Each Trade or Business

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule.

SUMMARY: This document contains final regulations that provide guidance on how an exempt organization subject to the unrelated business income tax determines if it has more than one unrelated trade or business, and, if so, how the exempt organization calculates unrelated business taxable income. The final regulations also clarify that the definition of ''unrelated trade or business'' applies to individual retirement accounts. Additionally, the final regulations provide that inclusions of ''subpart F income'' and ''global intangible low-taxed income'' are treated in the same manner as dividends for purposes of determining unrelated business taxable income. The final regulations affect exempt organizations that are subject to the unrelated business income tax.

DATES:

Effective date: The final regulations are effective on December 2, 2020.

Applicability date: For dates of applicability, see §§ 1.170A–9(k)(3), 1.509(a)–3(o), 1.512(a)–1(h), 1.512(a)–6(i), 1.512(b)–1(a)(3), 1.512(b)–1(g)(5), and 1.513–1(h).

FOR FURTHER INFORMATION CONTACT: Jonathan A. Carter at (202) 317–5800 or Stephanie N. Robbins at (202) 317–4086 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document amends the Income Tax Regulations (26 CFR part 1) by adding final regulations under section 512(a)(6) of the Internal Revenue Code (Code). Section 512(a)(6) was added to the Code by section 13702 of Public Law 115–97, 131 Stat. 2054 (2017), commonly referred to as the Tax Cuts and Jobs Act (TCJA). Section 512(a)(6) requires an exempt organization subject to the unrelated business income tax under section 511 (UBIT) that has more than one unrelated trade or business, to calculate unrelated business taxable income (UBTI), separately with respect to each such trade or business including for purposes of determining any net operating loss (NOL) deduction.

In August 2018, the Department of the Treasury (Treasury Department) and the IRS released Notice 2018–67 (2018–36 IRB 409 (Sept. 4, 2018)), which discussed and solicited comments regarding various issues arising under section 512(a)(6) and set forth interim guidance and transition rules relating to that section. The Treasury Department and the IRS received 24 comments in response to Notice 2018–67.

On April 24, 2020, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–106864–18) in the **Federal Register** (85 FR 23172) that proposed regulations to provide guidance regarding how an exempt organization subject to UBIT (hereinafter referred to as an exempt organization) determines if it has more than one unrelated trade or business, and, if so, how the exempt organization calculates UBTI under section 512(a)(6) (proposed regulations). No public hearing was requested or held. The Treasury Department and the IRS received 17 comments in response to the proposed regulations.

The proposed regulations reserved two issues for additional consideration. The first issue relates to the allocation of expenses, depreciation, and similar items shared between an exempt activity and an unrelated trade or business or between more than one unrelated trade or business. The second issue relates to changes made to the section 172 NOL deduction by the Coronavirus Aid, Relief, and Economic Security Act, Public Law 116–136, 134 Stat. 281 (2020) (CARES Act). The Treasury Department and the IRS anticipate publishing a separate notice of proposed rulemaking that will address these issues.

After consideration of the comments received, the proposed regulations are adopted as modified by this Treasury Decision. The major areas of comment and the revisions to the proposed regulations are discussed in the following Summary of Comments and Explanation of Revisions. The comments are available for public inspection at *www.regulations.gov* or on request. Other minor, non-substantive modifications made to the proposed regulations and adopted in these final regulations are not discussed in the Summary of Comments and Explanation of Revisions.

Summary of Comments and Explanation of Revisions

These final regulations provide guidance on how an exempt organization determines if it has more than one unrelated trade or business, and, if so, how the exempt organization calculates UBTI under section 512(a)(6). The final regulations also clarify that the definition of ''unrelated trade or business'' in section 513(b) applies to individual retirement accounts and that inclusions of subpart F income and global intangible low-taxed income are treated in the same manner as dividends for purposes of section 512.

1. Separate Unrelated Trade or Business

Consistent with section 512(a)(6) and the proposed regulations, the final regulations provide that an exempt organization with more than one unrelated trade or business must compute UBTI separately with respect to each unrelated trade or business, without regard to the specific deduction in section 512(b)(12), including for purposes of determining any NOL deduction.

a. NAICS 2-Digit Codes Retained

The proposed regulations generally provided that an exempt organization must identify each of its separate unrelated trades or businesses using the first two digits of the North American Industry Classification System code (NAICS 2-digit code) that most accurately describes the unrelated trade or business. Most commenters agreed with the proposed regulations' adoption of NAICS 2-digit codes over NAICS 6-digit codes, which Notice 2018–67, for purposes of interim guidance, provided was a reasonable way to identify separate trades or businesses. One commenter discussed how the use of NAICS 2-digit codes balances legislative intent of not allowing the losses from one unrelated trade or business to offset the income from another unrelated trade or business with the need for an administrable and efficient method of identifying separate unrelated trades or businesses. Other commenters agreed that NAICS 2-digit codes offer the most administrable and least burdensome method of identifying separate unrelated trades or businesses for both exempt organizations and the IRS.

One commenter disagreed with the use of NAICS 2-digit codes to identify separate unrelated trades or businesses. This commenter noted that, in passing the TCJA, Congress intended to limit exempt organizations' use of tax benefits that are unrelated to their tax-exempt purpose or purposes, and the commenter asserted that the proposed regulations reversed this congressional intent by identifying separate unrelated trades or businesses using the twenty broad categories provided by NAICS 2-digit codes. This commenter

recommended instead that the rules relating to the qualified business deduction under section 199A for identifying a separate trade or business should be used for purposes of section 512(a)(6). The regulations under section 199A provide that the term ''trade or business'' has the same meaning as in section 162. The commenter contended that enough case law exists with respect to section 162 to define ''trade or business'' and that the section 199A regulations have provided practitioners with enough experience to identify a trade or business using this definition.

The final regulations do not adopt the approach taken by the section 199A regulations as a method of identifying separate unrelated trades or businesses for purposes of section 512(a)(6) because, although sections 199A and 512(a)(6) were both enacted as part of the TCJA, they serve different purposes. Section 199A, in part, provides individuals, estates, and certain trusts a deduction of up to 20 percent of business income from certain domestic trades or businesses. Such taxpayers might be engaged in one or more trades or businesses for which they may be entitled to the section 199A deduction. For purposes of computing the section 199A deduction, taxpayers are required to determine the specific lines between trades or business to ensure that only qualified items of income and expense traced to each qualified trade or business are used to compute the deduction and that the W–2 wage and unadjusted basis immediately after acquisition (UBIA) limitations are properly applied. Therefore, the section 199A regulations look to section 162 to determine how these lines should be drawn. By contrast, section 512 looks to section 162 to determine whether a trade or business exists but employs a simplified regime to identify separate unrelated trades or businesses under section 512(a)(6) for exempt organizations because they are not primarily engaged in section 162 for-profit trades or businesses. The regime also applies for a more limited purpose, that is preventing exempt organizations from using losses of one unrelated trade or business to offset the gains of any other unrelated trade or business, and uniformly to all of an exempt organization's separate unrelated trades or businesses. The Treasury Department and IRS believe that using NAICS 2-digit codes in this context provides an objective means to identify separate trades or businesses consistent with Congress's intent without imposing an undue burden on exempt organizations. Accordingly, the final regulations under section 512(a)(6) do not adopt this comment.

b. No Additional Methods of Identifying Separate Unrelated Trades or Businesses

One commenter recommended that NAICS 2-digit codes be used as a safe-harbor and that a facts and circumstances test be applied as the primary method of identifying separate unrelated trades or businesses. This commenter asserted that a facts and circumstances test would be more consistent with other parts of the Code (including the regulations under section 199A) and would provide a more flexible framework for variations in activities across exempt organizations. This commenter proposed considering multiple factors for identifying separate trades or businesses that would include the interdependence of the activities, the geographic location of the activities, and the relationship the exempt organization has with the operation of the activity. The commenter opined that a facts and circumstances test would help alleviate any inequity caused by section 512(a)(6).

As explained both in Notice 2018–67 and the preamble to the proposed regulations, Congress did not provide any explicit criteria for determining whether an exempt organization has ''more than one unrelated trade or business'' or for identifying ''separate'' unrelated trades or businesses for purposes of calculating UBTI in accordance with section 512(a)(6). The Joint Committee on Taxation (JCT) noted that ''it is intended that the Secretary issue guidance concerning when an activity will be treated as a separate unrelated trade or business for purposes of [section 512(a)(6)].'' Staff of the Joint Committee on Taxation, General Explanation of Public Law 115–97 (December 2018), at 293 (General Explanation). Notice 2018–67 stated that the Treasury Department and the IRS would like to set forth a more administrable method than a facts and circumstances test for identifying separate unrelated trades or businesses. Nonetheless, the Treasury Department and the IRS considered a facts and circumstances test as a method of identifying separate unrelated trades or businesses in response to comments received following the enactment of section 512(a)(6) and again in response to Notice 2018–67. The factors suggested by commenters, and previously considered, generally were derived from other Code provisions, such as sections 132, 162, 183, 414, and 469. However, these Code provisions primarily consider whether an activity is a trade or business and not whether one trade or business is ''separate'' from another. Accordingly, the Treasury Department and the IRS continue to consider these Code provisions, alone or in conjunction with each other, as unhelpful models for identifying separate trades or businesses for purposes of section 512(a)(6).

It continues to be the case that adoption of a facts and circumstances test, as the only identification method or in addition to a safe harbor using NAICS 2-digit codes, would increase the administrative burden on exempt organizations in complying with section 512(a)(6) because a fact-intensive analysis would be required with respect to each unrelated trade or business. Additionally, adoption of a facts and circumstances test would offer exempt organizations less certainty and likely result in inconsistency among exempt organizations conducting more than one unrelated trade or business because of differing approaches exempt organizations would take in applying such a test. Also, a facts and circumstances test would increase the administrative burden on the IRS, which, upon examination, must perform the same fact-intensive analysis with respect to each of the unrelated trades or businesses identified by the exempt organization for purposes of calculating UBTI. Accordingly, the final regulations do not adopt a facts and circumstances test in addition to or in place of NAICS 2-digit codes as a method of identifying separate unrelated trades or businesses for purposes of section 512(a)(6).

c. Identifying the Appropriate NAICS 2-Digit Code

The proposed regulations provided that an exempt organization's separate unrelated trades or businesses are determined based on the applicable NAICS 2-digit code. Before an exempt organization can identify its ''separate'' unrelated trades or businesses, it must first determine whether it regularly carries on unrelated trades or businesses within the meaning of sections 511 through 514. Section 1.513–1(a) clarifies that, unless one of the specific exceptions of section 512 or 513 applies, gross income of an exempt organization is includible in the computation of UBTI if: (1) It is income from a trade or business; (2) such trade or business is regularly carried on by the organization; and (3) the conduct of such trade or business is not substantially related (other than through the production of funds) to the organization's performance of its exempt functions. Accordingly, the final regulations provide that an exempt organization determines whether it carries on unrelated trades or

businesses by applying sections 511 through 514. Under the final regulations, the exempt organization then identifies its separate unrelated trades or businesses for purposes of section 512(a)(6) using the methods described in the final regulations. With respect to most unrelated trade or business activities, an exempt organization determines whether those activities are separate unrelated trades or businesses for purposes of section 512(a)(6) based on the most accurate NAICS 2-digit codes describing the activities.

Several commenters requested additional guidance regarding how to choose the ''most accurate'' NAICS 2-digit code. These commenters suggested that strict adherence to NAICS 2-digit codes can result in unrelated trade or business activities that the exempt organization considers to be one unrelated trade or business being separated into two or more unrelated trades or businesses. Other commenters requested that aggregation of NAICS 2-digit codes be allowed in certain circumstances. The commenters provided examples of unrelated trade or business activities that they considered to be one unrelated trade or business but that may be identified as more than one unrelated trade or business when using NAICS 2-digit codes.

For example, one commenter stated that an organization operating a gift shop that sells clothing, electronics, and books in a bricks-and-mortar store and online would report those activities under two different NAICS 2-digit codes—one for the sale of clothing and electronics (44) and one for books and online sales (45). Another example provided by a commenter is a museum that provides catering services, valet parking, and personal property rentals as part of a package for special events, such as weddings, held on its premises. The commenter noted that the museum may be required to identify these activities using three different NAICS 2-digit codes—one for catering (72), one for parking (81), and one for rentals (53). The commenter posited that the museum should be able to treat this activity as one trade or business based on a reasonable and common sense understanding of the service provided (hosting an event), rather than the various components of the provided services.

The Treasury Department and the IRS note that NAICS 2-digit codes aggregate trade or business activities into only 20 separate trades or businesses, compared to the more than 1,000 trades or businesses identified at the NAICS 6-digit code level. Like the proposed regulations, the final regulations provide that a separate unrelated trade or business is identified by the NAICS 2-digit code that most accurately describes the exempt organization's trade or business activity. In addition, the final regulations add that this determination is based on the more specific NAICS code, such as at the 6-digit level, that describes the activity that it conducts. The final regulations also state that the descriptions in the current NAICS manual (available at *www.census.gov*) of trades or businesses using more than two digits of the NAICS codes are relevant in this determination. In response to commenter examples, the final regulations incorporate a rule used in NAICS for identifying certain industries [1] and provide that, in the case of the sale of goods, both online and in stores, the separate unrelated trade or business is identified by the goods sold in stores if the same goods generally are sold both online and in stores.

With respect to the museum example, the Treasury Department and the IRS note that income from activities that is appropriately characterized as income from rentals is generally exempt from UBTI under section 512(b)(3). The analysis of whether an activity produces rental income depends, in part, on whether other services are provided by the exempt organization in connection with the possible rental activity (such as providing space for a wedding). To the extent other services are provided, income from the use of space may cease to be rent from real property and instead take on the character of the services provided. *See* § 1.512(b)–1(c)(5). Exempt organizations already need to do this analysis of the facts and circumstances to determine their UBTI. Similarly, whether services provided in connection with hosting an event should be aggregated or not depends on the facts and circumstances, including the language of the contract or contracts, the services provided, who is providing the services, etc. It is possible that the activities could be separate trades or businesses based on the fragmentation rule contained in section 513(c) and § 1.513–1(b) (''[a]ctivities of producing or distributing goods or performing services from which a particular amount of gross income is derived do not lose identity as trade or business merely because they are carried on within a larger aggregate of similar activities or within a larger complex of other endeavors which may, or may not, be related to the exempt purposes of the organization'').

Because the NAICS at the 2-digit code level aggregates all trade or business activities into only 20 separate trades or businesses, many trade or business activities that could be considered separate trades or businesses, such as the provision of food or lodging, are already aggregated into broad categories (NAICS code 72 includes both lodging and food services) and therefore treated as one trade or business under the final regulations. Accordingly, if an exempt organization determines that, based on the facts and circumstances, its trade or business activities must be separated into two or more unrelated trades or businesses under NAICS 2-digit codes, the Treasury Department and the IRS view that result as appropriate to achieve the balance of tax administrability and carrying out the purposes of section 512(a)(6). Thus, under the final regulations, if trade or business activities would be best described by different NAICS 2-digit codes, those activities should be identified using different NAICS 2-digit codes and treated as separate unrelated trades or businesses.

In addition, consistent with the proposed regulations, the final regulations continue to provide that the NAICS 2-digit code must identify the separate unrelated trade or business in which the exempt organization engages (directly or indirectly). The NAICS 2-digit code cannot describe activities the conduct of which are substantially related to the exercise or performance by such organization of its charitable, educational, or other purpose or function constituting the basis for its exemption under section 501 (or, in the case of an organization described in section 511(a)(2)(B), to the exercise or performance of any purpose or function described in section 501(c)(3)). For example, a college or university described in section 501(c)(3) or 511(a)(2)(B) cannot use the NAICS 2-digit code for educational services to identify all of its separate unrelated trades or businesses, and a qualified retirement plan described in section 401(a) cannot use the NAICS 2-digit code for finance and insurance to identify all of its unrelated trades or businesses.

Also consistent with the proposed regulations, the final regulations continue to provide that an organization will report each NAICS 2-digit code only once. The Treasury Department and the IRS note that this rule permits exempt organizations to aggregate trade or business activities that may occur in

[1] The NAICS code for ''Electronic Shopping and Mail-Order Houses'' provides that ''Store retailing or a combination of store retailing and nonstore retailing in the same establishment—are classified in Sector 44–45, Retail Trade, based on the classification of the store portion of the activity.''

different geographic locations. The final regulations include the same example as provided by the proposed regulations—the pharmacies operated in different geographic locations that are one unrelated trade or business for purposes of section 512(a)(6) because the pharmacy trade or business is identified using one NAICS 2-digit code.

d. Changing NAICS 2-Digit Codes

The proposed regulations generally provided that, once an organization has identified a separate unrelated trade or business using a particular NAICS 2-digit code, the organization cannot change the NAICS 2-digit code describing that separate unrelated trade or business unless two requirements are met. First, the exempt organization must show that the NAICS 2-digit code chosen was due to an unintentional error. Second, the exempt organization must show that another NAICS 2-digit code more accurately describes the unrelated trade or business. The preamble to the proposed regulations stated that the instructions to the Form 990–T, ''Exempt Organization Business Income Tax Return,'' would be updated to describe how an exempt organization notifies the IRS of a change in a NAICS 2-digit code due to an unintentional error.

At least one commenter requested clarification regarding what is meant by ''unintentional error.'' Commenters also suggested that the final regulations should include additional circumstances in which exempt organizations can change the NAICS 2-digit code describing a separate unrelated trade or business. Several commenters explained that the nature of a separate unrelated trade or business may change or evolve to the extent that the unrelated trade or business would be more accurately reported under a different NAICS 2-digit code. One commenter likened this shift in trade or business activities to the commencement of a new unrelated trade or business. Accordingly, these commenters recommended that an exempt organization be permitted to change the NAICS 2-digit code identifying a separate unrelated trade or business if a change in the unrelated business activity results in it being better described by a different NAICS 2-digit code. Finally, one commenter requested that a code change be permitted if the exempt organization's tax preparer reasonably believes that an unrelated trade or business activity is more accurately described by a different NAICS 2-digit code.

Several commenters also requested clarification of the process for reporting an erroneous code. One commenter recommended that the instructions to the Form 990–T clarify that an exempt organization should provide such notification to the IRS on the Form 990–T—including an explanation of the change and any necessary supporting information—and that such change would be effective on the first day of the taxable year beginning after the taxable year for which the Form 990–T providing such notification is filed. This commenter also questioned whether reconciliation was required for the prior taxable year or years in which the erroneous code was used and, if so, how an adjustment resulting from such reconciliation would be applied.

In response to these comments, the final regulations remove the restriction on changing NAICS 2-digit codes. Instead, the final regulations require an exempt organization that changes the identification of a separate unrelated trade or business to report the change in the taxable year of the change in accordance with forms and instructions. *See* section 6012(a)(2) and § 1.6012–2(e). The final regulations clarify that a change in identification of a separate unrelated trade or business includes the changed identification of the separate unrelated trade or business with respect to a partnership interest that was incorrectly designated as a qualifying partnership interest (discussed in part 2.b of this Summary of Comments and Explanation of Revisions). To report the change in identification, the final regulations require an organization to provide certain information with respect to each separate unrelated trade or business the identification of which changes: The identification of the separate unrelated trade or business in the previous taxable year, the identification of the separate unrelated trade or business in the current taxable year, and the reason for the change. The Treasury Department and the IRS anticipate that the instructions to the Form 990–T will be revised for taxable years for which the final regulations are effective to provide instructions regarding where and how changes in identification are reported. The effect on NOLs caused by changes of the identification of separate unrelated trades or businesses are discussed in part 6.d of this Summary of Comments and Explanation of Revisions.

e. Transition From NAICS 6-Digit Codes to NAICS 2-Digit Codes

The preamble to the proposed regulations provided that, for taxable years beginning before the date the proposed regulations are published in the **Federal Register** as final regulations, an exempt organization may rely on a reasonable, good-faith interpretation of sections 511 through 514, considering all the facts and circumstances, when identifying separate unrelated trades or businesses for purposes of section 512(a)(6). The preamble to the proposed regulations provided that an exempt organization could rely on the proposed regulations in their entirety or, alternatively, the methods of aggregating or identifying separate trades or businesses provided in Notice 2018–67, which provided that a reasonable, good-faith interpretation included using NAICS 6-digit codes.

One commenter recommended that the final regulations confirm that an exempt organization that reported separate unrelated trades or businesses using NAICS 6-digit codes in taxable years beginning prior to the exempt organization's first taxable year for which the final regulations are effective can reclassify their activities using NAICS 2-digit codes without having to report an unintentional error.

As discussed in the Applicability Dates section of this preamble, these final regulations are applicable to taxable years beginning on or after December 2, 2020. Although an exempt organization may have used NAICS 6-digit codes to identify its separate unrelated trades or businesses in taxable years beginning before this date, the transition from NAICS 6-digit codes to NAICS 2-digit codes does not require the reporting of a code change because the exempt organization will be using the same NAICS code to identify its separate unrelated trades or businesses—just with fewer digits. The move from NAICS 6-digit codes to NAICS 2-digit codes may result in the combination of NOLs if an exempt organization has trade or business activities that would be separate unrelated trades or businesses if identified using NAICS 6-digit codes but would be one unrelated trade or business if identified using NAICS 2-digit codes. An exempt organization may choose, but is not required, to amend Forms 990–T filed prior to December 2, 2020 to report separate unrelated trades or businesses using NAICS 2-digit codes.

f. No De Minimis Exception Provided

The preamble to the proposed regulations discussed one comment with respect to Notice 2018–67 that suggested the Treasury Department and the IRS adopt a de minimis exception for exempt organizations reporting less than $100,000 of gross UBTI. The preamble to the proposed regulations explained that the Treasury Department

and the IRS declined to adopt the comment because section 512(a)(6) does not provide discretionary authority for the Treasury Department and the IRS to establish a de minimis exception. Further, the preamble to the proposed regulations explained that, even at a lower threshold, a de minimis rule would be contrary to the stated congressional intent of not permitting exempt organizations to use losses from one unrelated trade or business to offset the gains from another unrelated trade or business.

One commenter on the proposed regulations nonetheless recommended the adoption of a de minimis exception. This commenter proposed that an exempt organization with less than $10,000 of total gross revenues from all unrelated trade or business activities be permitted to treat all its unrelated trades or businesses as one trade or business for purposes of section 512(a)(6). For exempt organizations with more than $10,000 of total gross revenues from all unrelated trade or business activities, the commenter suggested aggregation of all separate unrelated trades or businesses with less than $1,000 of total gross revenues. The commenter reasoned that exempt organizations with less than $10,000 of total gross revenues from unrelated trade or business activities likely lack the resources necessary to comply with section 512(a)(6).

The commenter attempted to refute the argument that the Treasury Department and the IRS lack the authority to promulgate a de minimis exception by noting that the Treasury Department and the IRS already exercised discretion by permitting exempt organizations to treat their activities in the nature of investments as a separate unrelated trade or business for purposes of section 512(a)(6). The commenter cites the JCT General Explanation as confirmation that the Treasury Department and the IRS are authorized to permit the aggregation of separate unrelated trades or businesses.

Permitting the aggregation of certain investment activities is an administrative rule premised on the difficulty an exempt organization partner may experience in certain situations in obtaining the information needed to determine whether the trades or businesses conducted by the partnership are separate unrelated trades or businesses with respect to the exempt organization partner (see part 2 of this Summary of Comments and Explanation of Revisions for a more in depth discussion). By contrast, permitting the aggregation of ''de minimis'' separate unrelated trades or businesses is contrary to the congressional intent of not permitting exempt organizations to offset the losses from one unrelated trade or business with the gains from another, without regard to the amount of the gross receipts in either trade or business. Finally, the concept of a de minimis amount of UBTI is incompatible with the fragmentation rule in section 513(c); § 1.513–1(b). That is, the fragmentation rule requires the identification of unrelated trade or business activities no matter the size.

To the extent that smaller exempt organizations may have difficulty complying with section 512(a)(6), the Treasury Department and the IRS expect that adoption of NAICS 2-digit codes, as opposed to NAICS 6-digit codes, may relieve much of this burden because smaller exempt organizations are unlikely to have numerous unrelated trades or businesses under these final regulations. Furthermore, under § 1.6012–2(e), an exempt organization is required to file Form 990–T only ''if it has gross income, included in computing [UBTI] for such taxable year, of $1,000 or more.'' This filing threshold, which applies regardless of the number of separate unrelated trades or businesses conducted by the exempt organization, serves as a de minimis rule for small exempt organizations. Accordingly, the Treasury Department and the IRS do not adopt this comment in the final regulations for these reasons as well as the reasons cited in the preamble to the proposed regulations.

g. Allocation of Directly Connected Deductions

i. In General

Section 512(a)(1) permits an exempt organization with an unrelated trade or business to take the deductions allowed under chapter 1 of the Code (chapter 1) that are directly connected with the carrying on of such unrelated trade or business. Section 512(a)(3) similarly permits a social club described in section 501(c)(7), a voluntary employees' beneficiary association (VEBA) described in section 501(c)(9), or a supplemental unemployment benefits trust (SUB) described in section 501(c)(17) to take the deductions allowed under chapter 1 that are directly connected with the production of gross income (excluding exempt function income). To the extent that an exempt organization may have items of deduction that are shared between an exempt activity and an unrelated trade or business, § 1.512(a)–1(c) provides special rules for allocating such expenses. For example, if facilities are used both to carry on exempt activities and to conduct unrelated trade or business activities, then expenses, depreciation, and similar items attributable to such facilities must be allocated between the two uses on a reasonable basis (reasonable basis standard).

The preamble to the proposed regulations noted that an exempt organization with more than one unrelated trade or business must not only allocate shared expenses among exempt and taxable activities as described in § 1.512(a)–1(c) but also among separate unrelated trades or businesses. Accordingly, the proposed regulations incorporated the existing allocation standard in § 1.512(a)–1(c) for purposes of section 512(a)(6). No comments were received regarding this approach. Accordingly, the final regulations continue to provide that an exempt organization with more than one unrelated trade or business must allocate deductions between separate unrelated trades or businesses using the reasonable basis standard described in § 1.512(a)–1(c).

ii. The Unadjusted Gross-to-Gross Method Unreasonable in Certain Circumstances

The preamble to the proposed regulations did, however, describe the concerns of the Treasury Department and the IRS regarding the administrability of the reasonable basis standard. The preamble to the proposed regulations announced that the Treasury Department and the IRS would continue to consider whether the reasonable basis standard should be retained and announced the intention to publish a separate notice of proposed rulemaking. As an initial matter, however, the proposed regulations stated that allocation of expenses, depreciation, and similar items using an unadjusted gross-to-gross method is not reasonable. In general, a gross-to-gross method of allocation uses a ratio of gross income from an unrelated trade or business activity over the total gross income from both unrelated and related activities generating the same indirect expenditures. The percentage resulting from this ratio is used to determine the percentage of the shared costs attributable to the unrelated trade or business activity (or activities). If a price difference exists between the provision of a good or service to different populations and no adjustment is made, the gross-to-gross ratio may be described as ''unadjusted.''

Several commenters asserted that the unadjusted gross-to-gross method should not be considered unreasonable.

Of these commenters, two stated that the gross-to-gross method can be reasonable if there is no price difference for goods or services provided in related and unrelated activities or if adjustments are made for any price differences. One commenter further argued that no allocation method should be per se unreasonable because what is unreasonable with respect to one set of facts and circumstances may be reasonable with respect to another.

In response to these commenters' recommendations, the final regulations clarify that allocation of expenses, depreciation, and similar items is not reasonable if the cost of providing a good or service in a related and an unrelated activity is substantially the same, but the price charged for that good or service in the unrelated activity is greater than the price charged in the related activity and no adjustment is made to equalize the price difference for purposes of allocating expenses, depreciation, and similar items based on revenue between related and unrelated activities. For example, if a social club described in section 501(c)(7) charges nonmembers a higher price than it charges members for the same good or service, but does not adjust the price of the good or service provided to members for purposes of allocating expenses, depreciation, and similar items attributable to the provision of that good or service, the allocation method is not reasonable.

The Action on Decision (AOD) relating to *Rensselaer Polytechnic Institute* v. *Commissioner* stated that the IRS would not litigate the reasonableness of an allocation method ''until the allocation rules of [§ 1.512(a)–1(c)] are amended.'' 732 F.2d 1058 (2d Cir. 1984), *aff'g* 79 T.C. 967 (1982); AOD 1987–014 (Jun. 18, 1987). The final regulations amend the rules of § 1.512(a)–1(c) and, as discussed in the Applicability Dates section of this preamble, are effective for taxable years beginning on or after December 2, 2020. Accordingly, the IRS rescinds the AOD to the limited extent of any allocation method that fails to equalize price differences between related activities and unrelated trade or business activities for such taxable years. The IRS will continue to refrain from litigating the reasonableness of other allocation methods pending the publication of further guidance, which the Treasury Department and the IRS continue to consider and expect to publish in a separate notice of proposed rulemaking.

2. Activities in the Nature of Investments

The proposed regulations treat an exempt organization's activities in the nature of an investment (investment activities) as a separate trade or business for purposes of section 512(a)(6). Several commenters repeated the suggestion previously made in response to Notice 2018–67 that the Treasury Department and the IRS should not treat an exempt organization's investment activities as an unrelated trade or business, and therefore the income and losses from these activities should not be considered for purposes of applying section 512(a)(6). The preamble to the proposed regulations explained that the Treasury Department and the IRS concluded that the structure and purposes of sections 511 through 514 indicate that an exempt organization's investment activities are an unrelated trade or business for purposes of section 512(a)(6), although certain income from such investment activities (investment income) is excluded from the calculation of UBTI under modifications in section 512(b). The Treasury Department and the IRS also noted that the language of section 512(a)(6)(B) states an organization's total UBTI is the sum of the UBTI computed for each separate unrelated trade or business under section 512(a)(6)(A). To conclude that investment income is not included in the separately computed UBTI under section 512(a)(6)(A) would be to remove such income entirely from UBTI under section 512(a)(6)(B), even when no modification in section 512(b) applies to the income. Nothing in the legislative history or the statute suggests that Congress intended to amend the items of income that are taxable under section 511. Accordingly, the final regulations continue to treat an exempt organization's investment activities that are subject to UBIT as a separate unrelated trade or business for purposes of section 512(a)(6).

a. Exclusive List of Investment Activities

The proposed regulations provided an exclusive list of an exempt organization's investment activities that may be treated as a separate unrelated trade or business for purposes of section 512(a)(6). Under the proposed regulations, for most exempt organizations, such investment activities are limited to: (i) Qualifying partnership interests (see part 2.b of this Summary of Comments and Explanation of Revisions); (ii) qualifying S corporation interests (see part 3.a of this Summary of Comments and Explanation of Revisions); and (iii) debt-financed properties (see part 2.d of this Summary of Comments and Explanation of Revisions).[2] Although commenters recommended modifications to the rules regarding the individual items included in this list, no commenters objected to the treatment of these items as investment activities. Accordingly, the final regulations adopt the list of investment activities provided in the proposed regulations without change.

Nonetheless, some commenters recommended that this exclusive list be expanded to include specified payments from controlled entities that are included in UBTI under section 512(b)(13) (discussed in part 2.a.i of this Summary of Comments and Explanation of Revisions) and certain amounts from controlled foreign corporations that are included in UBTI under section 512(b)(17) (discussed in part 2.a.ii of this Summary of Comments and Explanation of Revisions).

i. Specified Payments From Controlled Entities

Section 512(b)(13)(A) requires an exempt organization, referred to as a ''controlling organization,'' that receives or accrues (directly or indirectly) a specified payment from another entity which it controls, referred to as a ''controlled entity,'' to include such payment as an item of gross income derived from an unrelated trade or business to the extent such payment reduces the net unrelated income of the controlled entity (or increases any net unrelated loss of the controlled entity). *See also* § 1.512(b)–1(l)(1). Section 512(b)(13)(C) defines the term ''specified payment'' as any interest, annuity, royalty, or rent. Accordingly, section 512(b)(13) treats certain amounts that would ordinarily be excluded from the calculation of UBTI under section 512(b)(1), (2), and (3) as income derived from an unrelated trade or business.

The proposed regulations provided that, if an exempt organization controls another entity (within the meaning of section 512(b)(13)(D)), the specified payments from that controlled entity will be treated as gross income from a separate unrelated trade or business for purposes of section 512(a)(6). If a controlling organization receives specified payments from two different controlled entities, the proposed regulations treated the payments from each controlled entity as separate unrelated trades or businesses.

[2] Special rules discussed in part 4 of this Summary of Comments and Explanation of Revisions apply to social clubs described in section 501(c)(7).

Two commenters recommended that income included in UBTI under section 512(b)(13) should be part of the investment activities trade or business under section 512(a)(6). These commenters noted that different fact patterns can produce different tax results because of the interaction between section 512(b)(13) and the debt-financed property rules of section 514. For example, one commenter provided a series of examples in which a wholly owned taxable subsidiary rented space from its exempt organization parent in a debt-financed property owned by the parent.

Section 1.514(b)–1(b)(2)(ii) of the current regulations states that section 514 does not apply to amounts specifically taxable under other provisions of the Code, such as rents and interest from controlled organizations includible pursuant to section 512(b)(13). Thus, if a controlling organization leases debt-financed property to a controlled organization, the amount of rents includible in the controlling organization's UBTI shall first be determined under section 512(b)(13), and only the portion of such rents not taken into account by operation of section 512(b)(13) are taken into account by operation of section 514. *See* § 1.512(b)–1(l)(5)(ii). Because the regulations provide a clear ordering rule that sets section 512(b)(13) income apart from the rules of section 514, section 512(b)(13) taxable income can never be debt-financed investment income.

The Treasury Department and the IRS considered in the preamble to the proposed regulations whether specified payments should be included with an exempt organization's investment activities and concluded that this treatment would be inconsistent with the purpose of section 512(b)(13)(A), which is to prevent a controlled entity from gaining a competitive advantage (in contravention of the purposes of section 512) through making deductible payments to a controlling organization that is exempt from tax. *See* S. Rep. No. 91–552, at 73 (1969) (explaining that certain ''rental'' arrangements between exempt organizations and taxable subsidiaries ''[enable] the taxable [subsidiary] to escape nearly all of its income taxes''). Consistent with this purpose, section 512(b)(13)(A) treats specified payments as income from an unrelated trade or business only ''to the extent such payment reduces the net unrelated income of the controlled entity (or increases any net unrelated loss of the controlled entity).'' Additionally, the required degree of control of the controlling organization over the controlled entity indicates that the controlled entities are not a part of the controlling organization's otherwise appropriately characterized investment activities.

Alternatively, if specified payments are not included with an exempt organization's investment activities, these commenters requested that specified payments from any source be treated as one unrelated trade or business for purposes of section 512(a)(6). The commenters asserted that the aggregation of specified payments would reduce the incentive to restructure financial transactions to obtain more favorable tax results. One commenter set out an example in which the UBTI from the separate unrelated trades or businesses for specified payments received from two controlled entities of an exempt organization differed under section 512(b)(13) depending on whether the exempt organization owned both subsidiaries directly or one subsidiary directly and the other subsidiary indirectly through the first subsidiary. The commenter asserted that aggregating the UBTI from all the controlled entities would create the same tax result for all exempt organizations with these facts regardless of the structure of the subsidiaries and the rental payments.

The Treasury Department and the IRS continue to view specified payments as not appropriately characterized as part of an exempt organization's investment activities. Furthermore, because section 512(b)(13) views specified payments as stemming from the trade or business activity of the controlled entity rather than from its investment activities, the Treasury Department and the IRS decline to adopt the suggestion that all specified payments be treated as one unrelated trade or business for purposes of section 512(a)(6). Rather, because section 512(b)(13)(A) provides that specified payments from a controlled entity are income derived from an unrelated trade or business, the final regulations adopt the proposed regulations regarding specified payments without modification.

ii. Certain Amounts From Controlled Foreign Corporations

Section 512(b)(17) requires any amount included in gross income under section 951(a)(1)(A) to be included as an item of gross income derived from an unrelated trade or business to the extent the amount so included is attributable to insurance income (as defined in section 953) which, if derived directly by the exempt organization, would be treated as gross income from an unrelated trade or business. Section 953(a)(1) defines ''insurance income'' as any income that (A) is attributable to the issuing (or reinsuring) of an insurance or annuity contract, and (B) would (subject to certain modifications not relevant here) be taxed under subchapter L of chapter 1 if such income were the income of a domestic insurance company. Thus, section 512(b)(17) ''applies a look-through rule in characterizing certain subpart F insurance income for unrelated business income tax purposes.'' H. R. Rep. No. 104–586 (1996), at 137.

The proposed regulations treated the provision of insurance by all controlled foreign corporations (CFCs) as one trade or business, regardless of whether such insurance income is received from more than one CFC, which is consistent with how NAICS would categorize the provision of insurance (52—Finance and Insurance). However, the proposed regulations did not permit the aggregation of an exempt organization's insurance income included in UBTI under section 512(b)(17) with any insubstantial commercial-type insurance activities conducted directly by the exempt organization because the CFC, not the exempt organization, is engaged in the activity giving rise to the insurance income included in UBTI under section 512(b)(17). The insurance activity described in section 512(b)(17) is not attributed to the exempt organization and thus is distinguishable from any commercial-type insurance activity engaged in directly by the exempt organization.

One commenter recommended that amounts included in income under section 512(b)(17) should be part of an exempt organization's investment activities. This commenter questioned the statement in the preamble to the proposed regulation that ''the required degree of control of the exempt organization over the controlled foreign corporation indicates that the exempt organization's interest in a controlled foreign corporation is probably not part of the exempt organization's otherwise appropriately characterized investment activities.'' The commenter explained that, with respect to insurance income specifically, the required ownership by United States shareholders for CFC status is reduced to 25 percent from the usual 50 percent. The commenter asserted that an exempt organization shareholder therefore could hold less than a 10 percent interest in a CFC that as a whole is owned by United States shareholders. The commenter stated that the low percentage of ownership necessary to have such amounts included in UBTI should warrant inclusion with an exempt organization's

investment activities, based on the similarity to the ownership percentages for qualifying partnership interest status discussed in part 2.b of this Summary of Comments and Explanation of Revisions. However, another commenter recommended retention of the rules in the proposed regulations for amounts included in income under section 512(b)(17).

As explained in the preamble to the proposed regulations, the reasons for not treating amounts included in income under section 512(b)(17) as an exempt organization's investment activities extend beyond the amount of control the exempt organization may have over the CFC. In particular, that preamble explained that insurance income included in UBTI under section 512(b)(17) should not be treated as gross income from an exempt organization's investment activities because the provision of insurance generally is an unrelated trade or business. *See* section 501(m) (providing that, in the case of an exempt organization described in section 501(c)(3) or (4) that does not provide commercial-type insurance as a substantial part of its activities, the activity of providing commercial-type insurance is treated as an unrelated trade or business (as defined in section 513)). Further, the percentage interest prongs of the qualifying partnership interest rules, discussed in parts 2.b.iii and 2.b.iv.A of this Summary of Comments and Explanation of Revisions, serve as a proxy for an exempt organization's ability to obtain the information necessary to identify the underlying trade or business of the partnership. For amounts included in income under section 512(b)(17), the underlying trade or business is known because the only amounts included are from the insurance activity of the CFC. Thus, the same treatment of income under section 512(b)(17) is not needed for administrative convenience.

Accordingly, the final regulations adopt without change the proposed regulations regarding the treatment of amounts included in UBTI under section 512(b)(17) for purposes of section 512(a)(6).

b. Qualifying Partnership Interests

In general, for exempt organizations, the activities of a partnership are considered the activities of the exempt organization partners.[3] Specifically, section 512(c) states that if a trade or business regularly carried on by a partnership of which an exempt organization is a member is an unrelated trade or business with respect to such organization, such organization shall include its share of the gross income of the partnership in UBTI. However, commenters on both Notice 2018–67 and the proposed regulations explained the difficulty of obtaining information regarding the trade or business activities of lower-tier partnerships. Therefore, as a matter of administrative convenience for both the exempt organization and the IRS, the proposed regulations permitted, but did not require, an exempt organization to aggregate its UBTI from an interest in a partnership with more than one unrelated trade or business (including unrelated trades or businesses conducted by lower-tier partnerships) if it met certain requirements (qualifying partnership interest, or QPI). Additionally, the proposed regulations permitted the aggregation of any QPI with all other QPIs, resulting in the treatment of the aggregate group of QPIs (along with associated debt-financed income under section 514 and qualifying S corporation interests, both discussed in parts 2.d and 3.a, respectively, of this Summary of Comments and Explanation of Revisions) as a single ''investment activities'' trade or business for purposes of section 512(a)(6)(A).

The proposed regulations identified a partnership interest as a QPI if it met the requirements of either the de minimis test (discussed in part 2.b.iii of this Summary of Comments and Explanation of Revisions) or the control test (discussed in part 2.b.iv of this Summary of Comments and Explanation of Revisions). A few commenters recommended alternative or additional tests to identify a QPI. Three commenters suggested that the generally accepted accounting principles (GAAP) codified by the Financial Accounting Standards Board (FASB) should replace the de minimis and the control tests to identify partnership interests as QPIs. These commenters recommended that any interest that is reported as ''fair value'' under these standards should be considered a QPI and included as part of the exempt organization's investment activities. Two other commenters recommended that a partnership that uses an investment manager should be a QPI. For this purpose, one of these commenters recommended defining an investment manager as someone who is either (i) included in a listing of investment managers with the Securities and Exchange Commission (SEC), (ii) in the business of providing investment advice for compensation and manages at least $150 million in client assets, or (iii) has filed a Form D notice with the SEC with respect to the partnership at issue indicating that interests in such partnership are offered under an exemption from SEC registration requirements. Finally, one commenter provided a general list of facts and circumstances that should be considered when determining whether a partnership interest is a QPI, such as whether the exempt organization is a limited partner, whether the exempt organization has the right to be involved in the day-to-day management or operations of the partnership, and whether the exempt organization formed the partnership.

As noted in Notice 2018–67, the purpose of permitting the aggregation of QPIs is to reduce the administrative burden of obtaining information from the partnership regarding the trade or business activities of the partnership in which the exempt organization holds a modest interest, and particularly of lower-tier partnerships under such partnership. As stated in the preamble to the proposed regulations, the percentage interest level for QPIs was intended as a proxy to identify partnership interests in which the exempt organization does not significantly participate. 85 FR at 23180. Taking into account the comments received, the Treasury Department and the IRS have determined that, for purposes of section 512(a)(6), if the percentage interest level indicates that an exempt organization does not significantly participate in a partnership, the exempt organization is not likely to be able to easily obtain the information required to identify the trades or businesses conducted, directly or indirectly, by the partnership that are unrelated trades or businesses with respect to the exempt organization partner.

The recommendations of the commenters regarding alternate or additional methods to determine whether a partnership interest is a QPI do not provide administrable methods for proximately measuring an exempt organization's ability to obtain information about the partnership's trades or businesses. Under GAAP, an exempt organization accounts for a partnership interest using ''fair value'' if it does not control a partnership or have ''significant influence'' in the partnership or if it holds an interest the value of which is ''readily determinable.'' FASB, 2020, ASC par. 958–810–15–4. As discussed in more detail in part 2.b.iv.B of this Summary

[3] *See* sections 512(c), 513(a); § 1.513–1(d)(1) and (2); *Plumstead Theatre Society, Inc.* v. *Commissioner,* 74 T.C. 1324 (1980); 675 F.2d 244 (9th Cir. 1995); *Service Bolt & Nut Co. Profit Sharing Trust* v. *Commissioner,* 724 F.2d 519 (6th Cir.1983), *affg,* 78 T.C. 812 (1982); Rev. Rul. 98–15, 1998–1 C.B. 718.

of Comments and Explanation of Revisions, determining ''significant influence'' under GAAP is substantially similar to determining significant participation under the participation test. By FASB's own admission, however, determining significant influence is not always clear. FASB, 2020, ASC par. 323–10–15–7. Further, whether a partnership interest has a readily determinable value does not indicate whether an exempt organization has access to the information needed to identify trades or businesses conducted by the partnership that are unrelated trades or businesses with respect to the exempt organization partner. The de minimis and control tests provide a substantially similar standard to that found in GAAP that is more objective and that does not include additional factors outside the scope of the QPI test. Additionally, unlike the adoption of NAICS 2-digit codes, adopting GAAP would mean using a set of rules that are maintained and amended frequently by a non-governmental third party. Furthermore, GAAP does not always align with tax standards.

Similarly, the presence of an investment manager does not indicate whether an exempt organization can obtain information to identify separate unrelated trades or businesses conducted by a partnership. In addition, the requirements for being an investment manager, as outlined by the commenter, require reliance on an SEC system that is designed for purposes that do not align with the those of the QPI tests. As a result, the investment manager test does not satisfy the purpose of the QPI tests and the Treasury Department and the IRS do not adopt this suggestion. Finally, the facts and circumstances test suggested by commenters relies on factors that do not tend to relate to the exempt organization's ability to obtain the information from the partnership needed to identify separate unrelated trades or businesses and therefore do not advance the administrative convenience purpose of the QPI test. Accordingly, the Treasury Department and the IRS do not adopt these suggestions as a reliable method for identifying QPIs.

Other commenters suggested the inclusion of all limited partnerships or limited liability companies (LLCs) in which the exempt organization is not a general partner or managing member (regardless of the exempt organization's percentage interest or other participation in the partnership) as QPIs. As discussed in the preamble to the proposed regulations, the Treasury Department and the IRS decline to adopt this standard because of the variation in state law for determining non-managing member equivalent interests and the administrative burden that reliance on state law places on the IRS.

Accordingly, the Treasury Department and the IRS do not adopt the recommended alternative or additional methods for identifying a QPI.

i. Designation of a QPI

The proposed regulations provided that, once an organization designates a partnership interest as a QPI (in accordance with forms and instructions), it cannot thereafter identify the trades or businesses conducted by the partnership that are unrelated trades or businesses with respect to the exempt organization using NAICS 2-digit codes unless and until the partnership interest is no longer a QPI. For example, if an exempt organization has a partnership interest that is a QPI and the exempt organization designates that partnership interest as a QPI on its Form 990–T, the exempt organization cannot, in the next taxable year, identify the trades or businesses of the partnership that are unrelated trades or businesses with respect to the exempt organization using NAICS 2-digit codes. However, if, in a future taxable year, the exempt organization's partnership interest is no longer a QPI, then the exempt organization would be required to identify the trades or businesses of the partnership that are unrelated trades or businesses with respect to the exempt organization using NAICS 2-digit codes. No comments were received regarding this provision. Accordingly, the final regulations adopt the proposed regulations regarding the designation of QPIs without change.

ii. General Partner Prohibition

The proposed regulations clarified that any partnership in which an exempt organization is a general partner is not a QPI, regardless of the exempt organization's percentage interest. One commenter noted that, while related parties are considered for determination of the percentage interest prong of the control test, these same related parties are not considered when determining the general partner status of the exempt organization under the de minimis test or for determining control under the second prong of the control test. Thus, a related entity may be a general partner in or may control the partnership in which an exempt organization has an interest and such control by the related party would not affect the outcome under the proposed regulations.

The Treasury Department and the IRS agree with the commenter that the determination of whether an exempt organization is a general partner should include related organizations. Thus, the final regulations clarify that, if an organization the interest of which must be taken into account when determining the exempt organization's percentage interest for purposes of the first prong of the control test is a general partner in a partnership in which an exempt organization holds an interest, then such interest is not a QPI.

One commenter recommended that the per se prohibition against general partner status for a partnership interest to be a QPI should be extended to status as a managing member of a limited liability company (LLC). The Treasury Department and the IRS agree that the term ''partnership'' includes all entities, including LLCs, treated as partnerships for Federal tax purposes. Accordingly, an interest in an LLC treated as a partnership for Federal tax purposes can be a QPI. However, the rule in the proposed regulations precluding a general partner interest from being a QPI was intended to apply only to interests held by partners classified as general partners under applicable state law. The Treasury Department and the IRS do not believe it is appropriate to expand the per se prohibition to persons classified as managing members under applicable state law without the opportunity for further notice and comment, although managing members are unlikely to satisfy the participation test due to their significant participation in the LLC. Accordingly, the final regulations adopt the proposed regulation with the clarification that general partner status is determined under applicable state law.

iii. De Minimis Test

The proposed regulations provided that a partnership interest is a QPI that meets the requirements of the de minimis test if the exempt organization holds directly or indirectly no more than 2 percent of the profits interest and no more than 2 percent of the capital interest.

One commenter recommended removing the de minimis test. The Treasury Department and the IRS have concluded that the de minimis test reduces administrative burden by establishing a clear limit below which no other factors need to be considered for inclusion of such interest as a part of an exempt organization's investment activities. Therefore, the Treasury

Department and the IRS retain the de minimis test in the final regulations.

One commenter recommended that the percentage interest threshold of the de minimis test should be increased to 5 percent consistent with other sections of the Code and regulations. The commenter notes that, not only have other parts of the Code determined that 5 percent is sufficiently de minimis, but also that increasing the amount from 2 percent to 5 percent would reduce administrative burden by potentially increasing the number of partnership interests that would meet the requirements of the de minimis test.

The Treasury Department and the IRS do not adopt this commenter's suggestion for the following reasons. For purposes of administrative convenience, the de minimis test allows certain partnership investments to be treated as an investment activity and aggregated with other investment activities. Otherwise, as previously discussed in this section of the preamble, section 512(c) mandates that any partnership interest, even a de minimis interest, must be analyzed to determine whether it is an unrelated trade or business with respect to the exempt organization partner and, by extension, how many unrelated trades or businesses for purposes of section 512(a)(6). Accordingly, any exception made in the interest of the administrative convenience of taxpayers must be narrowly tailored to achieving that purpose.

Furthermore, under the control test, partnership interests that exceed 2 percent are QPIs if those interests meet the requirements of the control test (now renamed the participation test, as discussed in part 2.b.iv of this Summary of Comments and Explanation of Revisions). Many exempt organizations with partnership interests between 2 percent and 5 percent should be able to determine, without much additional burden, that they do not significantly participate in the partnership and thus the partnership interest is a QPI; thus, not much additional convenience would be gained for exempt organizations by increasing the de minimis percentage amount from 2 percent to 5 percent. On the other hand, increasing the percentage under which an exempt organization does not have to demonstrate a lack of significant participation to be able to treat the partnership interest as a QPI would extend the administrative convenience exception to identifying the separate unrelated trades or businesses of the partnership (in accord with section 513(c)) farther than necessary and undermine the statutory requirement of section 512(a)(6). Therefore, the final regulations follow the proposed regulations and provide that a partnership interest is a QPI that meets the requirements of the de minimis test if the exempt organization holds, directly or indirectly, no more than 2 percent of the profits interest and no more than 2 percent of the capital interest. Additionally, the final regulations clarify that the exempt organization must meet the percentage interest requirement of the de minimis rule during the exempt organization's taxable year with which or in which the partnership's taxable year ends.

iv. Control Test Renamed the ''Participation Test''

The proposed regulations provided that a partnership interest is a QPI that meets the requirements of the control test if the exempt organization (i) directly holds no more than 20 percent of the capital interest; and (ii) does not have control over the partnership. As previously discussed in this section, the QPI tests focus on determining whether an exempt organization significantly participates in a partnership, thereby indicating an ability to obtain the information needed from the partnership to determine whether a trade or business conducted by the partnership is an unrelated trade or business with respect to the exempt organization partner. To better reflect this intent, the control test has been renamed in these final regulations as the ''participation test.'' Accordingly, the final regulations modify the participation test so that a partnership interest is a QPI that meets the requirements of the participation test if the exempt organization (i) directly holds no more than 20 percent of the capital interest; and (ii) does not significantly participate in the partnership.

A. Percentage Interest

Numerous commenters made recommendations regarding the first prong of the control test, most of which recommended increasing the percentage threshold to 50 percent to conform with the definition of control in section 512(b)(13). These commenters noted that the 50 percent threshold for capital interest is more in line with other definitions of control found in the Code. Other commenters suggested that the percentage interest requirement be eliminated entirely because an exempt organization may control a partnership regardless of its percentage interest.

The final regulations retain the 20 percent threshold used in the proposed regulations. As explained in the preamble to the proposed regulations, the percentage interest prong of the control test was intended to identify partnership interests in which the exempt organization does not have the ability to significantly participate in any partnership trade or business and therefore may be considered an investment activity for purposes of section 512(a)(6). Although an exempt organization may not significantly participate in a partnership in which it has more than a 20 percent interest, the Treasury Department and the IRS note that, as an exempt organization's percentage interest in a partnership increases, so too does the exempt organization's ability to obtain the information necessary to identify the trades or businesses conducted by the partnership that are separate unrelated trades or businesses with respect to the exempt organization partner. Thus, the Treasury Department and the IRS have determined that, for purposes of this aspect of the administrative exception for investment activities, a 20 percent capital interest is a threshold below which the exempt organization may not be able to obtain the needed information if it does not otherwise significantly participate.

The preamble to the proposed regulations noted that the 20 percent threshold is consistent with the administrative exception found in the regulations under section 731 for certain investment activities. *See* section 731(c)(3)(C)(i) & § 1.731–2(e). Some commenters noted that this was not a relevant standard because section 731(c)(3)(C)(i) does not define control. Section 731 defines investment partnerships, in part, as any partnership that has never been engaged in a trade or business.

The regulations under section 731(c)(3)(C)(i) identify situations in which the trade or business activities of a lower tier partnership should not be attributed to an upper tier partnership for purposes of determining whether the upper tier partnership is engaged in a trade or business. Similarly, the QPI rules in the proposed regulations seek to determine when the trade or business of a partnership should not be attributed to the exempt organization such that the partnership may be counted as part of an investment activity rather than as the participation in any underlying trade or business. Thus, the purpose of the regulations under section 731 and the QPI rules in the proposed regulations is similar.

The 20 percent capital interest threshold is further supported by the GAAP standard for ''significant influence'' that some commenters

recommended as an alternative to the de minimis and participation tests (see parts 2.b.iii and 2.b.iv of this Summary of Comments and Explanation of Revisions). Due to the difficulty of the significant influence determination, GAAP provides that holding 20 percent voting stock in an investee is presumed, without more, to constitute a significant influence. FASB, 2020, ASC par. 323–10–15–8. The 20 percent voting stock standard in GAAP was written for determining whether the investor has ''significant influence'' in a corporation. FASB, 2020, ASC par. 323–10–15–5. For tax purposes, it is common in the Code, when applying corporate standards to partnerships, to substitute ''capital interest'' for ''voting stock.'' *See, e.g.,* sections 4943(c)(3), 6166(b), & 6038(e)(3). Thus, the 20 percent capital interest threshold in the proposed regulations is consistent with FASB's determinations of the percentage interest that represents ''significant influence,'' which is similar to the significant participation standard found in these regulations.

Accordingly, the final regulations retain the 20 percent capital interest threshold provided by the proposed regulations but clarify that the exempt organization must meet the percentage interest requirement for the exempt organization's taxable year with which or in which the partnership's taxable year ends.

No comments were received regarding how an exempt organization determines its percentage interest in a partnership. Therefore, consistent with the proposed regulations and for purposes of both the de minimis test and the participation test, the final regulations continue to provide that an exempt organization determines its percentage interest by taking the average of the exempt organization's percentage interest at the beginning and the end of the partnership's taxable year, or, in the case of a partnership interest held for less than a year, the percentage interest held at the beginning and end of the period of ownership within the partnership's taxable year. However, the final regulations clarify that, for purposes of the de minimis test, an exempt organization's profits interest in a partnership is determined in the same manner as its distributive share of partnership taxable income (see section 704(b) relating to the determination of the distributive share by the income or loss ratio, and §§ 1.704–1 through 1.704–4). For purposes of both the de minimis test and the participation test the final regulations provide that, in the absence of a provision in the partnership agreement, an exempt organization's capital interest in a partnership is determined on the basis of its interest in the assets of the partnership which would be distributable to such organization upon its withdrawal from the partnership, or upon liquidation of the partnership, whichever is the greater.[4]

B. Definition of ''Significant Participation''

Under the proposed regulations, a partnership interest met the requirements of the control test if the exempt organization holds no more than a 20 percent of the capital interest and does not control the partnership. The proposed regulations provided that all the facts and circumstances are relevant for determining whether an exempt organization controls a partnership. The proposed regulations clarified that the partnership agreement is among the facts and circumstances that may be considered when determining control. The proposed regulations also listed four specific circumstances that evidence control. Two of the circumstances focused on the exempt organization's ability to perform certain actions on its own. Specifically, the proposed regulations provided that an exempt organization controls a partnership if the exempt organization, by itself, may require the partnership to perform, or may prevent the partnership from performing, any act that significantly affects the operations of the partnership or has the power to appoint or remove any of the partnership's officers or employees or a majority of directors. The remaining two circumstances focused on whether any of the exempt organization's officers, directors, trustees, or employees have rights to participate in the management of the partnership at any time or to conduct the partnership's business at any time.

In essence, the proposed regulations provided a two-part test for determining control: (1) A general facts and circumstances test based on the well-defined concept in the Code of ''control,'' and (2) factors evidencing ''per se'' control. As discussed in the introduction to part 2.b.iv of this Summary of Comments and Explanation of Revisions, the Treasury Department and the IRS have renamed the ''control test'' the ''participation test'' to better capture the purpose of the test, which is to identify partnerships in which exempt organization partners significantly participate. However, unlike ''control,'' ''significant participation'' generally is not a defined term in the Code. A test considering all the facts and circumstances to determine whether an exempt organization partner significantly participates in a partnership could have a broader application than intended. Furthermore, a general facts and circumstances standard for a test that is not well-defined increases uncertainty and, as a result, the administrative burden on exempt organizations and the IRS. Therefore, the final regulations do not include a general facts and circumstances test as part of the significant participation prong of the participation test, but instead retain only the four factors, which, in the final regulations, evidence significant participation rather than control.

Some commenters stated that the list of factors indicating control was too broad. One commenter contended that the factors focusing on whether an officer, director, or employee of an exempt organization has rights to manage the partnership or conduct the business of the partnership should be removed entirely as the presence of these factors does not indicate control by the exempt organization. While the factors identified by this commenter and the factors other commenters characterized as too broad may not always represent control, these factors do indicate when an exempt organization participates in the partnership to an extent that would allow the exempt organization to obtain sufficient information to identify the underlying separate trades or businesses.

Another commenter suggested that the factors listed as indicating control may not always result in control, and thus, the factors listed should create a rebuttable presumption of control rather than being ''per se'' indicators of control. The Treasury Department and the IRS retain the factors listed in the proposed regulations as ''per se'' indicators of significant participation because the QPI rules, including the participation test, are designed to provide administrative convenience for both the IRS and exempt organizations. In this way, firm standards that indicate significant participation allow both the IRS and exempt organizations to have more certainty in the decision whether to include such interests with an exempt organization's investment activities. A rebuttable presumption would introduce more uncertainly, rely more on facts and circumstances, and be

[4] These clarifying rules for determining an exempt organization's partnership interest are consistent with longstanding rules in § 53.4943–3(c)(2) for purposes of a private foundation's determination of whether it has excess business holdings.

more difficult for both the IRS and exempt organizations to administer.

The Treasury Department and the IRS note that the factors provided in the regulations are similar to the factors indicating ''control'' and ''significant influence'' under FASB's codification of GAAP, which several commenters proposed as an alternative test. For partnership interests, GAAP determines that enough control exists to require the consolidation of partnership interests with the investor if the investor has substantive kick-out or participating rights. A kick-out right is the ability of limited partners to dissolve (liquidate) the limited partnership or otherwise remove the general partners without cause. FASB, 2020, ASC section 958–810–20. These rights are included, in the proposed regulations, in an exempt organization's ability to require, by itself, the partnership to perform, or prevent the partnership from performing, any act that significantly affects the operations of the partnership.

Further, under GAAP, certain participating rights are considered per se substantive rights and overcome the presumption of control by a general partner. These include:

- Selecting, terminating, and setting the compensation of management responsible for implementing the limited partnership policies and procedures; and
- Establishing operating and capital decisions of the limited partnership, including budgets, in the ordinary course of business. ASC paragraph 958–810–25–22.

These substantive participating rights are similar to an exempt organization's ability to appoint or remove, by itself, any of the partnership's officers or employees or a majority of directors; or its officers, directors, trustees, or employees' rights to conduct the partnership's business at any time, respectively. As such, these substantive participating rights found in GAAP are covered by the four factors listed in the proposed regulations as indicating control (here renamed significant participation).

Additionally, some of the factors relevant to ''significant influence'' included in GAAP are representation on the board, the ability to participate in the policy-making process, and the interchange of managerial personnel. FASB, 2020, ASC par. 323–10–15–6. These factors are also similar to the factors in the proposed regulations, which focus on whether an exempt organization's officers, directors, trustees, or employees have rights to participate on the partnership's board or participate in management of the business. Moreover, the ability to participate in the policy-making process could stem from the investor's ability to require the partnership to perform, or prevent the partnership from performing, any act that significantly affects the operations of the partnership. Consequently, the factors for determining ''significant influence'' under GAAP are also covered by the factors listed in the proposed regulations.

Accordingly, the Treasury Department and the IRS have concluded that the list of factors indicating significant participation (renamed from ''control'' as used in the proposed regulations) is consistent with other standards recommended by commenters for making similar determinations. Therefore, the Treasury Department and the IRS continue to believe that, for purposes of the administrative exception for investment activities, the factors listed in the proposed regulations appropriately identify partnerships in which the exempt organization significantly participates such that it can obtain the information needed to identify the trades or businesses conducted by the partnership that are separate unrelated trades or businesses with respect to the exempt organization.

Commenters pointed out that the exercise of certain rights common to all partners in a partnership may be construed to come within the ambit of the list of factors indicating significant participation. Specifically, these commenters explained that an exempt organization with voting rights equal to those of a large number of other limited partners might be considered to be able to prevent the actions of a partnership if the vote requires a unanimous vote. The Treasury Department and the IRS agree with these commenters that the ability to prevent an action of the partnership due to a unanimous vote requirement or through minority consent rights was not intended to be covered by the proposed regulations. Accordingly, the final regulations modify the proposed regulations' treatment of the ability of an exempt organization, by itself, to prevent a partnership from performing an act as a factor that indicates significant participation. As modified, the final regulations provide that an exempt organization significantly participates in a partnership if—

- The exempt organization, by itself, may require the partnership to perform, or prevent the partnership from performing (other than through a unanimous voting requirement or through minority consent rights), any act that significantly affects the operations of the partnership;
- Any of the exempt organization's officers, directors, trustees, or employees have rights to participate in the management of the partnership at any time;
- Any of the organization's officers, directors, trustees, or employees have rights to conduct the partnership's business at any time; or
- The organization, by itself, has the power to appoint or remove any of the partnership's officers or employees or a majority of directors.

Some commenters recommended that instead of, or in addition to, a list of factors that indicate significant participation, the regulations should provide a list of powers that do not indicate significant participation, such as the ability to remove or replace a fund manager who manages partnership investments, to approve the selection or removal of a general partner, to appoint a member of an advisory board of the partnership, to withdraw from a partnership, or to dissolve or terminate the partnership.

The Treasury Department and the IRS expect that, because the participation test no longer includes a general facts and circumstances test, the need to define actions that do not evidence significant participation is significantly reduced or eliminated. An exempt organization need not consider rights or powers other than the four specifically listed in the participation test when determining whether a partnership interest is a QPI. Accordingly, the Treasury Department and the IRS decline to adopt the suggestion to include a list of powers that do not indicate significant participation.

C. Combining Related Interests

The proposed regulations provided a rule to address situations in which an exempt organization may control a partnership through the aggregation of interests (aggregation rule). The aggregation rule in the proposed regulations applied only for purposes of the control test and not for purposes of the de minimis test. The aggregation rule in the proposed regulations required an exempt organization to consider the interests of supporting organizations (as defined in section 509(a)(3)) and controlled entities (as defined in section 512(b)(13)) in the same partnership. The preamble to the proposed regulations stated that the Treasury Department and the IRS would continue to consider whether the aggregation of the interests of supporting organizations is appropriate in the circumstance in which the

exempt organization is a supported organization that has little to no control over its supporting organizations.

A supporting organization is characterized as a Type I, Type II, or Type III supporting organization depending on its relationship with its supported organization. The supporting organization may be (i) operated, supervised, or controlled by (Type I), (ii) supervised or controlled in connection with (Type II), or (iii) operated in connection with (Type III), its supported organization.

For a Type I relationship to exist, a supported organization must have a substantial degree of direction over the policies, programs, and activities of its supporting organization. The relationship of the supported organization to the Type I supporting organization is comparable to that of a parent and subsidiary, where the subsidiary is under the direction of, and accountable or responsible to, the parent organization.

For a Type II relationship to exist, there must be common supervision or control by the persons supervising or controlling both the supporting organization and the publicly supported organizations to ensure that the supporting organization will be responsive to the needs and requirements of the publicly supported organizations. The relationship of the supported organization to the Type II supporting organization is comparable to that of a brother and sister, where the supporting organization and the supported organization are subject to common control. *Polm Family Foundation, Inc.* v. *United States,* 655 F. Supp. 2d 125, 128 (D.C. Cir. 2009) (quoting *Cockerline Memorial Fund* v. *Commissioner,* 86 T.C. 53, 59 (1986)).

For a Type III relationship to exist, a supporting organization must, among other things, maintain significant involvement in the operations of a supported organization or provide support on which the supported organization is dependent. A Type III supporting organization can either be functionally integrated or non-functionally integrated. A functionally integrated Type III supporting organization can support its supported organization through engaging in activities substantially all of which directly further the exempt purposes of the supported organization, being the parent of the supported organization, or by supporting certain types of governmental supported organizations. A functionally integrated Type III supporting organization is a parent of the supported organization if the supporting organization exercises a substantial degree of direction over the policies, programs, and activities of the supported organization and a majority of the officers, directors, or trustees of the supported organization is appointed or elected, directly or indirectly, by the governing body, members of the governing body, or officers (acting in their official capacity) of the supporting organization. A non-functionally integrated Type III supporting organization provides financial support to the supported organization that meets the distribution requirements found in § 1.509(a)–4(i)(5)(ii).

Two commenters addressed whether partnership interests of related supporting organizations should be considered in determining the supported organization's percentage interest for purposes of determining whether the supported organization meets the control test. One commenter recommended that none of the partnership interests of a supporting organization should be considered when determining the supported organization's percentage interest. Another made the same recommendation but only with respect to Type III supporting organizations.

An exempt organization with more than one unrelated trade or business may be a supporting organization or a supported organization. If the exempt organization is a supported organization, the exempt organization, or individuals that control the exempt organization, may control the investment activities (including any partnership interests) of its Type I or Type II supporting organizations due to the parent/subsidiary relationship required for a Type I relationship to exist or the brother/sister relationship required for a Type II relationship to exist. In any event, these close relationships increase the likelihood that the exempt organization can obtain the information about its Type I or Type II supporting organization's partnership investments and that the exempt organization significantly participates in the partnership, even if indirectly. Accordingly, the final regulations continue to require an exempt organization that is a supported organization to include the partnership interests of its Type I or II supporting organizations when determining whether its partnership interests of the supported organization meet the percentage interest threshold of the participation test.

On the other hand, in the case of a Type III supporting organization, the exempt organization that is a supported organization is required to have a ''significant voice'' in the investment policies of its Type III supporting organization; nevertheless, depending on the basis for this Type III relationship, this relationship may not permit the supported organization to obtain detailed information regarding its Type III supporting organization's partnership interests or to significantly participate in the partnership. In the case of a Type III supporting organization that is the parent of its supported organizations, the relationship between the supported and supporting organizations is similar to that of a Type I supporting organization, except the supporting organization controls the supported organizations instead of the opposite. Due to this close relationship, the final regulations continue to require the aggregation of partnership interests held by a Type III supporting organization that is the parent of its supported organizations for the purposes of determining whether the supported organization's partnership interest meets the percentage interest threshold of the participation test. However, the interests held by nonparent Type III supporting organizations are not so aggregated.

One commenter recommended adding additional interests to the list of related interests that must be considered when determining percentage interest for purposes of the control test. This commenter recommended including related persons within the definition of section 267(b)(9) and ''controlled taxpayers'' within the principles of section 482 to the list of organizations with which partnership interests must be aggregated. The same commenter also recommended adding indirect interests owned by an exempt organization for the purposes of determining the organization's percentage interest.

As mentioned previously, the QPI rules were created to reduce the administrative burden of obtaining the information needed to determine whether trades or businesses conducted—directly or indirectly—by the partnership are separate unrelated trades or businesses with respect to the exempt organization partner. The addition of the interests recommended to be included by this commenter would significantly increase the administrative burden of the rule but would not necessarily capture interests that demonstrate an increased ability for the exempt organization to obtain the information needed to identify separate underlying trades or businesses. Accordingly, the Treasury Department and the IRS do not adopt these recommended additions to the aggregation rule. Accordingly, the final regulations provide that, when

determining an organization's percentage interest for purposes of the participation test (formerly the control test), the interests of a supporting organization (other than a Type III supporting organization that is not a parent of its supported organizations) or a controlled entity in the same partnership are taken into account.

v. Look-Through Rule

The proposed regulations provided that, if an exempt organization does not control a partnership in which the exempt organization holds a direct interest (directly-held partnership interest) but the directly-held partnership interest is not a QPI because the exempt organization holds more than 20 percent of the capital interest, any partnership in which the exempt organization holds an indirect interest through the directly-held partnership interest (indirectly-held partnership interest) may be a QPI if the indirectly-held partnership interest meets the requirements of the de minimis test (look-through rule). Accordingly, the proposed regulations permitted (but did not require) an exempt organization to aggregate the UBTI from de minimis indirectly-held QPIs with its directly-held QPIs. However, the proposed look-through rule did not apply to indirectly-held QPIs that do not meet the requirements of the de minimis test but might meet the requirements of the control test (now renamed participation test).

Several commenters recommended expanding the look-through rule to permit use of the control test for indirectly-held partnership interests and to permit use of the look-through rule even if the exempt organization controls the directly-held partnership. These commenters stated that, even if an exempt organization controls a directly-held partnership, if the lower-tier partnerships meet the de minimis test or the control test, an exempt organization would be prevented from controlling the lower-tier partnerships. Further, the commenters noted that, preventing the use of such look-through rules would treat organizations holding the same level and type of partnership interests differently depending on whether they owned them directly or indirectly. Another commenter, however, stated that the look-through rule is unhelpful and that it is extremely difficult, if not impossible, to determine ownership percentages in lower-tier partnerships, especially multiple tiers down.

Based on these comments, the final regulations do not prevent application of the look-through rule if the exempt organization significantly participates in the directly-held partnership. The final regulations otherwise retain the look-through rule for indirectly-held partnership interests that meet the requirements of the de minimis test with regard to the exempt organization. Additionally, the final regulations expand application of the look-through rule to indirectly-held partnership interests that meet the requirements of the participation test with regards to the immediately higher-tier partnership that owns interest in that partnership. Thus, for purposes of the look-through rule, the participation test will apply tier-by-tier to the exempt organization's indirectly-held partnership interests. The regulations explain how the second prong of the participation test—the significant participation prong—applies within this context and provides an example of the application of this test.

vi. Grace Period

The preamble to the proposed regulations stated that the Treasury Department and the IRS recognize that an exempt organization may not be aware of changes in its partnership interest until it receives a Schedule K–1 (Form 1065) from the partnership at the end of the partnership's taxable year. In such a circumstance, it may be appropriate to permit a higher percentage interest in taxable years in which the increase in an exempt organization's percentage interest during a taxable year is the result of the actions of other partners. The Treasury Department and the IRS requested comments regarding whether a higher percentage interest should be permitted in taxable years in which the increase occurs as the result of the actions of other partners.

One commenter stated that private investment funds often admit limited partners in waves (''closings'') over the course of several months at the beginning of the fund's term. Therefore, the commenter recommended a phase-in period that would provide that the percentage interest in a newly formed partnership not be considered for purposes of the control test until the end of the partnership's initial closing period (as long as that period is no later than 18 months following the exempt organization becoming a partner). The final regulations do not adopt an initial phase-in period because the aggregation of an exempt organization's investment activities, including QPIs, is a rule of administrative convenience and a phase-in rule would increase the complexity of the rule. Additionally, as discussed in part 2.b.iv.A of this Summary of Comments and Explanation of Revisions, the final regulations adopt, without change, the rule that an exempt organization's percentage partnership interest is determined by averaging the exempt organization's percentage partnership interest at the beginning of the partnership's taxable year with its partnership percentage interest at the end of that same taxable year. Thus, an exempt organization's percentage interest may vary during a period but still meet the requirements of the participation test.

The commenter also recommended that an exempt organization be granted 90 days to reduce its interest in a partnership to the appropriate amount should its interest exceed that amount at the end of the year through the actions of other partners. Two other commenters recommended that an exempt organization should be permitted to count a partnership interest that exceeds the percentage interest threshold of the participation test due to the actions of other partners as a QPI for a period of time following that change in interest amount. One of the commenters recommended that such interests should be permitted to be QPIs through the end of the tax year in which it learns that the percentage interest exceeds the permitted threshold. The other commenter recommended that such interest should continue to be QPI through the later of (1) the end of the tax year immediately following the year an increase occurs through no fault of the E.O.; or (2) 120 days after the date on which the partnership issues the Schedule K–1.

The Treasury Department and the IRS agree that a change in an exempt organization's percentage interest in a partnership that is due entirely to the actions of other partners may present significant difficulties for the exempt organization. Further, requiring such an interest to be removed from the exempt organization's investment activities in one year but potentially included as a QPI in the next would create further administrative difficulty. Accordingly, the final regulations adopt a grace period that permits a partnership interest to be treated as meeting the requirements of the de minimis test or the participation test, respectively, in the exempt organization's prior taxable year if certain requirements are met.

The final regulations provide that a partnership interest that fails to meet the requirements of either the de minimis test or the participation test because of an increase in percentage interest in the organization's current taxable year may be treated as meeting the requirements of the test it met in the prior taxable year for the taxable year of the change if: (1) The partnership

interest met the requirements of the de minimis test or participation test, respectively, in the organization's prior taxable year without application of the grace period; (2) the increase in percentage interest is due to the actions of one or more partners other than the exempt organization; and (3) in the case of a partnership interest that met the requirements of the participation test in the prior taxable year, the interest of the partner or partners that caused the increase in percentage interest described in (2) was not combined for the prior taxable year and is not combined for the taxable year of the change with the exempt organization's partnership interest under the rules discussed in part 2.b.iv.C of this Summary of Comments and Explanation of Revisions. An exempt organization can treat such interest as a QPI in the taxable year that such change occurs, but the exempt organization would need to reduce its percentage interest prior to the end of the following taxable year to meet the requirements of either the de minimis test or the participation test in that succeeding taxable year for the partnership interest to remain a QPI.

vii. Reliance on Schedule K–1 (Form 1065)

The proposed regulations provided that, when determining an exempt organization's percentage interest for purposes of the de minimis test or the control test (now renamed the participation test), the exempt organization may rely on the Schedule K–1 (Form 1065) it receives from the partnership if the form lists the exempt organization's percentage profits interest or its percentage capital interest, or both, at the beginning and end of the year. However, the proposed regulations clarified that the organization may not rely on the form to the extent that any information about the organization's percentage interest is not specifically provided. For example, if the Schedule K–1 (Form 1065) an exempt organization receives from a partnership lists the organization's profits interest as ''variable'' but lists its percentage capital interest at the beginning and end of the year, the organization may rely on the form only with respect to its percentage capital interest. Generally, this information can be found in Part II, line J (partner's share of profit, loss, and capital), of Schedule K–1 (Form 1065). No comments were received with respect to reliance on the Schedule K–1 (Form 1065). Accordingly, the final regulations adopt these proposed regulations without change, other than minor edits for clarity.

Nonetheless, commenters made recommendations with respect to other aspects of the Schedule K–1 (Form 1065) and other partnership or S corporation forms. A few commenters recommended that updates be made to the regulations under section 6031 or on the forms and instructions of the Form 1065, ''U.S. Return of Partnership Income,'' or Form 1120–S, ''U.S. Income Tax Return for an S Corporation,'' including the respective Schedules K–1 provided to partners or S corporation shareholders. These commenters requested updates that would require partnerships to provide information to exempt organization partners (1) on the NAICS 2-digit codes of the underlying activity, (2) separately reporting debt-financed income, and (3) requiring a specific capital interest amount rather than stating ''various.'' Alternatively, another commenter specifically recommended that partnerships not be required to provide the NAICS 2-digit code of the underlying activity.

Section 6031(d) provides that partnerships must provide exempt organization partners with such information as is necessary to enable each partner to compute its distributive share of partnership income or loss from such trade or business in accordance with section 512(a)(1). Following the passage of section 512(a)(6), exempt organization partners will need additional information to compute their UBTI from partnerships under section 512(a)(1). The Treasury Department and the IRS have concluded that the requirement found in section 6031(d) is sufficient for requiring partnerships to provide this information. Accordingly, the Treasury Department and the IRS do not adopt any regulatory changes under section 6031 at this time. The IRS may amend the forms and instructions in the future, however.

viii. Additional Recommended Changes

A. Capital Account Threshold

One commenter recommended that a capital accounts threshold be added to the control test. The commenter recommended that the threshold be based on the average capital account amount throughout the year and that the threshold be $500,000. A capital account threshold does not further the purposes of the QPI tests. A capital accounts threshold added to the control test provided by the proposed regulations (now renamed the participation test) is not an effective proxy for an exempt organization's ability to obtain information from a partnership because the size of a capital account has no correlation to a partner's ability to participate in a partnership. Further, capital accounts can be calculated under various standards, which would result in an inconsistent application of such a rule. Additionally, if the commenter's level of $500,000 capital accounts were accepted, IRS data for the 2018 taxable year indicates that it would encompass over 75 percent of all partnerships held by exempt organizations. Such a threshold therefore likely would not serve as an additional limitation on the ability to use the participation test. Accordingly, the Treasury Department and the IRS do not adopt a capital accounts threshold as part of the participation test.

B. ERISA-Covered Trusts

One commenter recommended that QPI treatment be extended to all partnership interests held by trusts that are subject to the Employee Retirement Income Security Act of 1974, Public Law 93–406, 88 Stat. 829 (1974) (ERISA). The commenter stated that because the fiduciary duty and prohibited transaction rules under ERISA would make it difficult to operate a trade or business through the trust itself, or through an entity that is treated under ERISA as holding ''plan assets'' subject to ERISA, the primary source of UBTI for these plans is investment vehicles that are taxed as partnerships. In addition, the fiduciary and prohibited transaction rules (and related penalties) create an incentive for the investment vehicles to limit the participation of ERISA plans. If 25 percent or more of the value of any class of equity interests in a private investment fund is held by benefit plan investors, the plan assets of a benefit plan investor will generally include not only the plan's investment, but also an undivided interest in each of the underlying assets of the investment fund. Anyone who exercises authority or control with respect to the disposition of plan assets or who provides investment advice with respect to those assets will be a fiduciary of the investing plan. *See* 29 CFR 2510.3–101. Many investment funds seek to avoid this status by limiting ERISA plan investment or qualifying for an exemption. The commenter posited that under the proposed regulations, significant administration would be required to separate investments between QPIs and other partnerships that may be subject to the look-through rule or NAICS codes, and in which the ultimate, bottom-tier investments are almost certainly under the 2 percent ownership threshold for the de minimis test.

To the extent that ERISA-covered trusts' interests in partnerships meet either the de minimis or the participation tests, then those interests will be treated as investment activities. To the extent that the partnership interests of ERISA-covered trusts do not meet the de minimis or the participation test, nothing about ERISA-covered trusts suggests that they are in greater need of the administrative convenience provided by such tests. Consequently, the Treasury Department and the IRS do not adopt this recommendation.

C. Anti-Abuse Rule

One commenter noted that an exempt organization with a directly-held partnership interest in a partnership that is not a QPI (non-QPI partnership) could also have one or more indirectly-held partnership interests in that same partnership through interests that are QPIs (QPI partnerships), which would effectively permit the exempt organization to significantly participate in a partnership but structure its partnership interest such that most of the distributable share of the partnership's income, losses, etc. would be aggregated with its other investment activities. The commenter recommended requiring an exempt organization receiving income through a QPI partnership that derives income from a non-QPI interest in the same partnership to segregate that income from the ''investment activities'' trade or business and report it separately for each underlying trade or business.

Under the situation described by the commenter, an exempt organization's indirectly-held partnership interest (through a QPI partnership) in the non-QPI partnership would necessarily be limited by the fact that the exempt organization may own no more than 20 percent of the QPI partnership and the exempt organization cannot control the QPI partnership; therefore it would be difficult, and perhaps unlikely, for an exempt organization to actively arrange such a scenario for the purposes of avoiding the application of section 512(a)(6). Further, the application of such rule would reduce the administrative convenience that these rules seek to achieve. Accordingly, the Treasury Department and the IRS do not adopt the recommendation.

The same commenter, noting that such a rule would reduce the administrative burden of the QPI rules, recommended the creation of an anti-abuse rule in the alternative. The Treasury Department and the IRS recognize that some situations, similar to the situation posited by the commenter or otherwise, may exist whereby an exempt organization may arrange partnership structures to avoid application of section 512(a)(6). It is always the case that, upon examination, the IRS may determine whether partnership interests are QPIs under the application of the law to the facts and characterize such interests accordingly. Accordingly, the Treasury Department and the IRS do not consider a specific anti-abuse rule necessary for purposes of the QPI rules and the final regulations do not incorporate this comment.

c. Transition Rule

Both Notice 2018–67 and the proposed regulations permitted an exempt organization to treat each partnership interest acquired prior to August 21, 2018, that met the requirements of neither the de minimis test nor the control test, as one trade or business for purposes of section 512(a)(6), regardless of whether there was more than one trade or business directly or indirectly conducted by the partnership or lower-tier partnerships (transition rule). This transition rule was proposed to apply until the first day of the organization's first taxable year beginning after the date the proposed regulations are published as final regulations (transition period). The proposed regulations clarified that a partnership interest acquired prior to August 21, 2018, will continue to meet the requirement of the transition rule even if the exempt organization's percentage interest changes on or after August 21, 2018. Further, the proposed regulations provided that an exempt organization may apply either the transition rule or the look-through rule, but not both, to a partnership interest that meets the requirements for both rules.

Three commenters recommended that the transition rule become a grandfather rule such that any partnership interest meeting the requirements of the transition rule would be a single unrelated trade or business in perpetuity for purposes of section 512(a)(6). One commenter stated that the rationale for the transition rule outlined in Notice 2018–67 that ''[a] previously acquired partnership interest may be difficult to modify to the de minimis test or control test and the exempt organization may have to incur significant transaction costs to do so'' will continue to be an accurate reflection of the difficulty of transitioning such previously owned partnership interests even after the final regulations are published.

Changing the transition rule to a grandfather rule is contrary to the congressional intent of section 512(a)(6) to prevent losses of one unrelated trade or business from offsetting gains of another unrelated trade or business. Exempt organizations have been on notice since the announcement of the transition rule in Notice 2018–67 that the transition rule would sunset after publication of final regulations and have had over two years since the release of Notice 2018–67 to anticipate the requirement to account for the income from such partnership interests differently. The Treasury Department and the IRS disagree that the rationale for the transition rule justifies perpetually excluding previously held partnership interests from the application of section 512(a)(6) to the unrelated trade or business activities of the partnership. Accordingly, the Treasury Department and the IRS do not adopt the transition rule as a grandfather rule.

d. Unrelated Debt-Financed Income

The proposed regulations included unrelated debt-financed property or properties described in sections 512(b)(4) and 514 in the list of ''investment activities'' treated as a separate unrelated trade or business for purposes of section 512(a)(6). One commenter recommended that the reference to the definition of debt-financed property ''within the meaning of section 514'' exclude section 514(b)(1)(B) because that paragraph removes from the definition of debt-financed property any property that is used in the production of income from an unrelated trade or business and proposed § 1.512(a)–6(c)(1)(iii) includes income from debt-financed property in the ''investment activities trade or business.'' The commenter further recommended that ''debt-financed property'' exclude debt-financed property used in the production of income from an unrelated trade or business that is reported under a NAICS two-digit code by the exempt organization. Two other commenters recommended allowing exempt organizations to opt out of inclusion of debt-financed property as part of an exempt organization's investment activities and to instead include that income as part of a separate unrelated trade or business identified by the relevant NAICS 2-digit code.

Section 512(b)(4) includes as UBTI any unrelated debt-financed income as defined in section 514. As part of the definition of debt-financed property, section 514(b)(1)(B) provides that ''any property [is not debt-financed property] to the extent that the income from such property is taken into account in computing the gross income of any

unrelated trade or business'' without application of section 512(b)(4). For example, if an exempt organization runs a hotel, but it has taken out a loan to acquire the hotel, then the income from the hotel is UBTI regardless of section 512(b)(4) and the hotel is not ''debt-financed property.'' Sections 1.512(b)–1(c)(5) and 1.514(b)–1(b)(2)(ii). Thus, the income from the hotel is not ''debt-financed income.'' As a result, any income included in UBTI as ''debt-financed income'' necessarily derives from an activity that has otherwise been excluded from the definition of UBTI in section 512(a)(1), for reasons other than the exempt nature of the activity. Section 514 taxes otherwise nontaxable income, derived from leveraged income-producing assets, that are not related to an organization's exempt purposes. Debt-financed income is, therefore, of a different nature than income that is otherwise described in section 512(a)(1) and is more appropriately classified as investment rather than being tied to an underlying trade or business or NAICS 2-digit code.

Furthermore, allowing an exempt organization to elect to treat the debt-financed income as part of a 2-digit NAICS code, instead of including such income as part of an organization's investment activities, would not reduce the burden upon the exempt organization or the burden on the IRS. Such income would still need to be identified as debt-financed income and an additional determination of the underlying activity would also need to be made to determine a 2-digit NAICS code. Furthermore, the inconsistent treatment of debt-financed income by different exempt organizations would increase the administrative burden for the IRS.

Accordingly, the Treasury Department and the IRS adopt the proposed regulation regarding the treatment of debt-financed income without change.

3. S Corporation Interest Treated as an Interest in an Unrelated Trade or Business

For purposes of the unrelated business income tax, section 512(e) provides special rules applicable to S corporations. Section 512(e)(1)(A) provides that if an exempt organization permitted to be an S corporation shareholder (as described in section 1361(c)(2)(A)(vi) or (6)) holds stock in an S corporation, such interest will be treated as an interest in an unrelated trade or business. Thus, notwithstanding any other provision in sections 511 through 514, section 512(e)(1)(B) requires an exempt organization permitted to hold S corporation stock to take the following amounts into account in computing the UBTI of such exempt organization: (i) All items of income, loss, or deduction taken into account under section 1366(a) (regarding the determination of an S corporation shareholder's tax liability); and (ii) any gain or loss on the disposition of the stock in the S corporation.

a. Qualifying S Corporation Interests

As discussed in part 2.a.i of this Summary of Comments and Explanation of Revisions, the proposed and final regulations include qualifying S corporation interests (QSI) in an exempt organization's investment activities. The proposed regulations explained that an S corporation interest is a QSI if the exempt organization's ownership interest (by percentage of stock ownership) in the S corporation meets the requirements for a QPI—that is, the requirements of either the de minimis test or the control test (now renamed the participation test).

The final regulations provide greater clarity regarding how the QPI rules apply to S corporation interests. First, the final regulations provide a number of term substitutions. Specifically, the final regulations provide that, when applying the QPI rules to an S corporation interest, ''S corporation'' is substituted for ''partnership'' and ''shareholder'' or ''shareholders'' is substituted for ''partner'' or ''partners.'' When applying the de minimis test, ''no more than 2 percent of stock ownership'' is substituted for ''no more than 2 percent of the profits interest and no more than 2 percent of the capital interest'' and, when applying the participation test, ''no more than 20 percent of stock ownership'' is substituted for ''no more than 20 percent of the capital interest.'' When applying the reliance rule, ''Schedule K–1 (Form 1120–S)'' is substituted for ''Schedule K–1 (Form 1065).''

Second, the final regulations clarify that the rules regarding the determination of an exempt organization's capital interest and profits interest in a partnership do not apply for purposes of determining whether an S corporation interest is a QSI. Rather, the average percentage stock ownership is determinative.

Third, because of differences in the Schedule K–1 (Form 1065) and the Schedule K–1 (Form 1120–S), the final regulations clarify that an exempt organization can rely on the Schedule K–1 (Form 1120S) received from the S corporation if the form lists information sufficient to determine the exempt organization's percentage of stock ownership for the year. A Schedule K–1 (Form 1120–S) that reports ''zero'' as the organization's number of shares of stock in either the beginning or end of the S corporation's taxable year does not list information sufficient to determine the organization's percentage of stock ownership for the year. The Treasury Department and the IRS are considering whether revision of Schedule K–1 (Form 1120S) is needed to provide the information needed to determine whether an S corporation interest is a QSI.

Finally, the final regulations also clarify that a grace period may apply for changes in an exempt organization's percentage of stock ownership in an S corporation.

b. Nonqualifying S Corporation Interests

With the exception of QSIs, the proposed regulations applied the language of section 512(e)(1)(A) to provide that if an exempt organization owns stock in an S corporation, such S corporation interest will be treated as an interest in a separate unrelated trade or business for purposes of the proposed regulations. Similarly, the proposed regulations clarified that if an exempt organization owns two S corporation interests, neither of which is a QSI, the exempt organization will report two separate unrelated trades or businesses, one for each S corporation interest. The proposed regulations also provided that the UBTI from an S corporation interest is the amount described in section 512(e)(1)(B), which includes both the items of income, loss, or deduction taken into account under section 1366(a) and the gain or loss on the disposition of S corporation stock.

Two commenters recommended that an exempt organization with an S corporation interest should be permitted to look through that S corporation to the underlying trades or businesses and to classify those S corporation trades or business using NAICS 2-digit codes. One of these commenters suggested that this should be the general rule for all non-qualifying S corporation interests. The other commenter provided that such a rule should be an alternative to the rule requiring each S corporation interest to be treated as an interest in a separate unrelated trade or business. One of these commenters further recommended that income that would ordinarily be excluded under section 512(b)(1), (2), (3) or (5), but that is taxable because it is earned through an S corporation, should be included as part of the exempt organization's investment activities.

The final regulations adopt the proposed regulations regarding non-

qualifying S corporation interests without change. As discussed in the preamble to the proposed regulations, this treatment is consistent with the language of section 512(e)(1)(A), which treats an interest in an S corporation as an unrelated trade or business. Although the Treasury Department and the IRS considered whether to permit exempt organizations to look through the S-corporation and identify the separate unrelated trades or businesses conducted by the S-corporation using NAICS 2-digit codes as a matter of administrative convenience, the commenters to Notice 2018–67 noted that obtaining that information from the S corporation would be difficult. Accordingly, the Treasury Department and the IRS decline to adopt a rule that modifies the straightforward application of the language of section 512(e)(1)(A) and is not otherwise justified as a matter of administrative convenience to taxpayers or the IRS.

4. Social Clubs, Voluntary Employees' Beneficiary Associations, and Supplemental Unemployment Benefits Trusts

As discussed in the preamble to the proposed regulations, section 512(a)(3) provides a special definition of UBTI for social clubs, VEBAs, and SUBs.[5] Unlike an exempt organization subject to section 512(a)(1) which is taxed only on income derived from an unrelated trade or business, a social club, VEBA, or SUB is taxed on ''gross income (excluding exempt function income),'' which includes amounts excluded from the calculation of UBTI under section 512(a)(1), such as interest, annuities, dividends, royalties, rents, and capital gains. The preamble to the proposed regulations provided that, despite the differences between section 512(a)(1) and (3), a social club, VEBA, or SUB would determine whether it has more than one unrelated trade or business in the same manner as an exempt organization subject to section 512(a)(1). The final regulations adopt the same approach, as discussed in parts 4.a and b of this Summary of Comments and Explanation of Revisions.

a. Investment Activities

As discussed in part 2 of this Summary of Comments and Explanation of Revisions, the proposed regulations treated certain investment activities (that is, QPIs, QSIs, and debt-financed property or properties) as a separate unrelated trade or business for purposes of section 512(a)(6). Thus, because a social club, VEBA, or SUB determines whether it has more than one unrelated trade or business in the same manner as an exempt organization subject to section 512(a)(1), such an exempt organization would include the investment activities specifically listed in the proposed regulations as a separate unrelated trade or business for purposes of section 512(a)(6). However, because UBTI is defined differently for social clubs, VEBAs, and SUBs, the proposed regulations clarified that, in addition to other investment activities treated as a separate unrelated trade or business for purposes of section 512(a)(6), gross income from the investment activities of a social club, VEBA, or SUB also includes any amount that (i) would be excluded from the calculation of UBTI under section 512(b)(1), (2), (3), or (5) (that is, interest, annuities, dividends, royalties, rents, and capital gains) if the organization were subject to section 512(a)(1); (ii) is attributable to income set aside (and not in excess of the set aside limit described in section 512(a)(3)(E)), but not used, for a purpose described in section 512(a)(3)(B)(i) or (ii); or (iii) is in excess of the set aside limit described in section 512(a)(3)(E). The final regulations adopt the proposed investment activity rules specific to social clubs, VEBAs, and SUBs, without change as discussed in part 4.a.i and ii of this Summary of Comments and Explanation of Revisions.

In the preamble to the proposed regulations, the Treasury Department and the IRS requested comments on any unintended consequences, in areas other than UBIT, resulting from the treatment of investment activity of VEBAs and SUBs as an unrelated trade or business for purposes of section 512(a)(6). One commenter expressed a concern that these proposed rules could encourage VEBAs and SUBs to create more complicated investment structures (for example, increased use of blocker corporations) or that these rules could encourage VEBAs and SUBs to consider more conservative investment strategies than otherwise merited based on their asset values.

The commenter did not include any further elaboration on these general nontax concerns regarding the investment behavior of VEBAs and SUBs. Furthermore, the commenter did not offer a specific recommendation to address these general concerns other than its overall recommendation to not treat investment activities as an unrelated trade or business for purposes of section 512(a)(6). As discussed earlier in part 2 of this Summary of Comments and Explanation of Revisions, the Treasury Department and the IRS have concluded that the structure and purposes of sections 511 through 514 treat an exempt organization's investment activities as unrelated trade or business activities for purposes of section 512(a)(6). Accordingly, the final regulations adopt these provisions of the proposed regulations without change.

i. Amounts Described in Section 512(b)(1), (2), (3), and (5)

Social clubs, VEBAs, and SUBs generally must include interest, dividends, royalties, rents, and capital gains in UBTI under section 512(a)(3)(A) because the modifications in section 512(b)(1), (2), (3), and (5) are not available under section 512(a)(3). Nonetheless, such amounts may be excluded from UBTI if set aside (and not in excess of the set aside limit described in section 512(a)(3)(E)) for a purpose described in section 512(a)(3)(B)(i) or (ii).[6] Interest, dividends, royalties, rents, and capital gains generally are considered income from investment activities and, as stated in part 4 of this Summary of Comments and Explanation of Revisions, treated as one unrelated trade or business for purposes of section 512(a)(6). Accordingly, the proposed regulations provided that, for purposes of section 512(a)(6), UBTI from the investment activities of a social club, VEBA, or SUB includes any amount that would be excluded from the calculation of UBTI under section 512(b)(1), (2), (3), or (5) if the social club, VEBA, or SUB were subject to section 512(a)(1).

Commenters generally were in favor of this approach. Accordingly, the final regulations adopt this portion of the proposed regulations without change.

ii. Amounts Set Aside But Used for Another Purpose and Amounts in Excess of Account Limits

Section 512(a)(3)(B) provides that, if an amount which is attributable to income set aside for a purpose described in section 512(a)(3)(B)(i) or (ii) is used for a purpose other than one described therein, then such amount shall be included in UBTI under section 512(a)(3)(A). Furthermore, with respect to a VEBA or SUB, the amount set aside may not exceed the set aside limit under section 512(a)(3)(E) and any amount that exceeds this limit is UBTI under section 512(a)(3)(A).

[5] See § 1.512(a)–5, 84 FR 67370 (Dec. 10, 2019), for a discussion of the UBTI rules as they specifically apply to VEBAs and SUBs.

[6] As explained in the introduction to part 4 of this Summary of Comments and Explanation of Revisions, treating the investment activities of a social club, VEBA, or SUB as an unrelated trade or business for purposes of section 512(a)(6) does not affect the amounts that may be set aside under section 512(a)(3)(B)(i) or (ii).

As discussed in part 4.a.i of this Summary of Comments and Explanation of Revisions, the amounts that may be set aside under section 512(a)(3)(B)(i) or (ii) are income from the social club, VEBA, or SUB's investment activities. Therefore, the proposed regulations also provided that UBTI from the investment activities of a social club, VEBA, or SUB includes any amount that is attributable to income set aside (and not in excess of the set aside limit described in section 512(a)(3)(E)), but not used, for a purpose described in section 512(a)(3)(B)(i) or (ii) and also includes any amount in excess of the set aside limit described in section 512(a)(3)(E).

No comments were received on this section of the proposed regulations and it is therefore adopted as final.

b. Social Club Activities

i. Limitation on Investment Activities

Section 501(c)(7) requires that ''substantially all of the activities'' of an organization described therein be ''for pleasure, recreation, and other nonprofitable purposes.'' Accordingly, a social club has specific limits on the amount of nonexempt function income that may be earned without endangering its tax-exempt status. While the Code does not provide more detail, intended limits are described in legislative history. *See* S. Rep. No. 94–1318 (1976), at 4–5. Additionally, Congress did not intend social clubs to receive, within these limits, non-traditional unrelated business income. *Id.* at 4 (''It is not intended that these organizations should be permitted to receive . . . income from the active conduct of businesses not traditionally carried on by these organizations.''). Accordingly, consistent with Notice 2018–67, the proposed regulations provided that the QPI rule and the transition rule do not apply to social clubs because social clubs should not be invested in partnerships that would generally be conducting non-traditional, unrelated trades or businesses that generate more than a de minimis amount of UBTI. In this regard, a partnership interest meeting the requirements of the de minimis rule in these proposed regulations is not the same as a partnership interest generating only de minimis amounts of UBTI from non-traditional, unrelated trades or businesses.

One commenter recommended that social clubs should have access to the de minimis test for investments in partnerships. The commenter states that partnership holdings may include exclusively items that are described in section 512(b)(1), (2), (3), and (5) and that social clubs would have equal difficulty determining the underlying trade or business as other exempt organization investors.

The Treasury Department and the IRS do not adopt the commenter's recommendation for the following reasons. To the extent that a social club is invested in a partnership all of the holdings of which would be excluded under section 512(b)(1), (2), (3), and (5) if the social club were subject to section 512(a)(1), then all such income is part of the social club's investment activities trade or business without application of the de minimis test. To the extent that a social club holds, directly or indirectly, an interest in a partnership that is performing a non-traditional, unrelated trade or business, then under section 512(c) the social club itself is engaged in a non-traditional, unrelated trade or business. Because a social club's nontraditional activities could jeopardize a social club's exemption, it is incumbent upon the social club to know the type and amount of such activities without regard to section 512(a)(6). Thus, the Treasury Department and the IRS do not consider the administrative convenience rationale supporting the QPI rule as relevant for social clubs and do not adopt the commenter's recommendation.

ii. Nonmember Activities

Under the proposed regulations, a social club with nonmember income is subject to the same rules for identifying its unrelated trades or businesses as an organization subject to the rules of section 512(a)(1). Further, as discussed in the preamble to the proposed regulations, a social club cannot use the NAICS 2-digit code generally describing golf courses and country clubs (71) to describe all its nonmember income because the NAICS code used must describe its separate unrelated trade or business and not the purpose for which it is exempt. While this code may describe some of a social club's nonmember income, such as greens fees, other NAICS codes may be more appropriate to describe other nonmember income, such as merchandise sales (45) and food and beverage services (72). Accordingly, a social club must identify its separate unrelated trades or businesses in accordance with the rule described in part 1 of this Summary of Comments and Explanation of Revisions, like an exempt organization subject to section 512(a)(1). See part 1.c of this Summary of Comments and Explanation of Revisions for a discussion of how to identify the appropriate NAICS 2-digit code.

Commenters again requested that a social club be permitted to treat all nonmember activities as one unrelated trade or business for purposes of section 512(a)(6). The commenters stated that separating a social club's nonmember activities into more than one unrelated trade or business would result in substantial administrative burden. The commenters describe the variety of activities in which social clubs engage, including food and beverage sales in club dining facilities and on club grounds (such as at pools or on golf courses and tennis courts); retail sales; greens fees; and space rental fees, whether or not they include substantial services. One commenter also stated that, because the treatment of UBTI for social clubs under section 512(a)(3) is different from that of other exempt organizations' treatment of UBTI under section 512(a)(1), using different rules to identify the separate unrelated trades or businesses for social clubs was reasonable. Finally, a commenter provided that, because social clubs are already capped at 15 percent of their revenue from nonmember activities, aggregating all nonmember income under that cap has a de minimis effect on taxable income while greatly decreasing the administrative burden of such organizations.

Section 512(a)(3) taxes all income, other than exempt function income, of the exempt organizations subject to that section, while section 512(a)(1) taxes only the income from the unrelated trades or businesses of all other exempt organizations. As a result, section 512(a)(3) captures a broader group of sources of income than under section 512(a)(1). Further, Congress has previously expressed a desire to limit the nonmember income of a social club to 15 percent of all income and to constrain further the non-traditional trades or businesses of a social club. *See* S. Rep. No. 94–1318, at 4. Social clubs would be in a more favorable tax position if social clubs were permitted to aggregate income that organizations subject to section 512(a)(1) would not be able to aggregate if they performed the same activities. The Treasury Department and the IRS are not persuaded that social clubs should have a more favorable position under section 512(a)(6) than other exempt organizations. Additionally, section 512(a)(6) does not specifically except social clubs, nor does it except a social club's nonmember income. Accordingly, the Treasury Department and the IRS do not adopt the recommendation to treat

all of a social club's nonmember income as a single unrelated trade or business.

One commenter recommended that social clubs be permitted to use the Uniform System of Financial Reporting for Clubs that is produced jointly by Hospitality Financial and Technology Professionals and Club Managers Association of America. This commenter stated that this system would better represent separate unrelated trades or businesses historically identified by social clubs.

The accounting system recommended by the commenter is a proprietary system that is not available for public use. Adopting this system as the required method of identifying a separate unrelated trade or business for social clubs would require all such clubs to purchase the materials of a third-party provider. Accordingly, the Treasury Department and the IRS do not adopt the Uniform System of Financial Reporting for Clubs as a method of identifying a separate unrelated trade or business for social clubs.

The final regulations adopt the proposed regulations' treatment of a social club's nonmember activities without change.

iii. Nonrecurring Events

The Treasury Department and the IRS recognize that UBTI within the meaning of section 512(a)(3) includes gross income without regard to a specific determination regarding the associated activities' qualification as an unrelated trade or business (within the meaning of section 513) because UBTI under section 512(a)(3) includes ''all gross income (excluding exempt function income).''

These final regulations generally require an exempt organization to identify its separate unrelated trades or businesses using the NAICS 2-digit code that most accurately describes each trade or business. Whether an infrequent or possibly nonrecurring event constitutes a separate unrelated trade or business or whether such event is part of another trade or business (including, in some cases, part of the social club's investment activities) depends on the facts and circumstances of each social club and the event at issue, including the scope of activities as part of the event. While such determination is not necessary for including such income in UBTI under section 512(a)(3), identification of separate unrelated trades or businesses is necessary for applying section 512(a)(6). In the preamble to the proposed regulations, the Treasury Department and the IRS requested comments regarding the particular facts and circumstances that should be considered by a social club when determining whether a non-recurring event should be treated as a separate unrelated trade or business, part of a larger trade or business, or as part of a social club's investment activities for purposes of section 512(a)(6).

Multiple commenters provided several facts and circumstances that might assist a social club in identifying the separate unrelated trade or business associated with the non-recurring activity. However, the Treasury Department and the IRS have determined that, due to the limited nature of these activities and the great variety of such circumstances, the inclusion of such a list of factors within the final regulations is not warranted at this time. Accordingly, the Treasury Department and the IRS do not adopt any additional factors for social clubs to consider when identifying the separate trade or business of the non-recurring activity. Social clubs can rely on the general rules in the final regulations for identifying a separate trade or business to identify the separate trade or business associated with non-recurring events.

iv. Activities Without a Profit Motive

As discussed in part 1 of this Summary of Comments and Explanation of Revisions, § 1.513–1(b) provides that ''for purposes of section 513 the term trade or business has the same meaning it has in section 162, and generally includes any activity carried on for the production of income.'' The requirement for a trade or business to have an intent to profit is further supported by case law. *See, e.g., Commissioner* v. *Groetzinger,* 480 U.S. 23, 35 (1987) (stating that, ''to be engaged in a trade or business, . . . the taxpayer's primary purpose for engaging in the activity must be for income or profit''). This profit motive requirement was applied to the unrelated trades or businesses of a social club in *Portland Golf Club* v. *Commissioner,* 497 U.S. 154 (1990) (finding that, under section 512(a)(3) prior to the enactment of section 512(a)(6), the golf club could use nonmember sales losses for food and drink to offset investment income only if the sales were motivated by an intent to profit, and in demonstrating the requisite profit motive, the golf club had to employ the same method of allocating fixed expenses as it used in calculating its actual loss).

One commenter on the proposed regulations requested that the Treasury Department and the IRS clarify that nonmember activities conducted without intent to profit are not unrelated trades or businesses. In the preamble to the proposed regulations, the Treasury Department and the IRS declined to address this comment in the proposed regulations because it is adequately addressed by existing precedent and cited to *Portland Golf.*

In response to the preamble of the proposed regulations, one commenter stated that a specific trade or business activity must be identified prior to determining whether it creates losses on a consistent basis. Given that the trade or business activity must first be identified, and that the proposed regulations prescribed the use of NAICS 2-digit codes for identifying a separate unrelated trade or business, the commenter noted that a social club must first identify the appropriate NAICS 2-digit code for a trade or business activity and determine whether the trade or business activity represented by that NAICS 2-digit code generates losses on a consistent basis (and thus may lack the requisite profit motive to be a trade or business at all for UBIT purposes). Under this analysis, the commenter recommended allowing exempt organizations to include, or exclude, certain activities from a trade or business based on the social club's internal determination that the activity lacks a profit motive.

The Treasury Department and the IRS agree that profit motive is relevant to determining whether an activity is a trade or business and that an exempt organization has a separate unrelated trade or business for purposes of section 512(a)(6) only if the activity being analyzed as separate is a trade or business. The Treasury Department and the IRS also agree that, for UBIT purposes, the appropriate level for determining whether a profit motive exists (based on the generation of consistent losses) with regard to an activity as a trade or business is the NAICS 2-digit level since the Treasury Department and the IRS have determined that the NAICS 2-digit codes appropriately identify separate unrelated trades or businesses.

However, the Treasury Department and the IRS do not adopt the commenter's recommendation to allow exempt organizations to exclude certain activities from the UBTI calculation based on the organization's assertion of a lack of intention to make a profit. In determining the lack of a profit motive, greater weight is given to objective facts than to a taxpayer's intent. *See, e.g.,* § 1.183–2(a). Thus, an exempt organization would need to demonstrate a factual lack of profit motive rather than claiming a lack of intent without any demonstrated losses. Furthermore, in light of the purpose and effect of

section 512(a)(6) to not permit losses from one trade or business to offset income from another trade or business, the commenter's recommendation would only benefit exempt organizations if the exempt organization could exclude income from a trade or business activity (first separated on the basis of the NAICS 2-digit code levels) from UBTI on an assertion that the exempt organization has no profit motive with regard to such activity notwithstanding the income from that activity. The Treasury Department and the IRS do not see any basis for providing such a rule.

5. Total UBTI and the Charitable Contribution Deduction

Consistent with section 512(a)(6), the proposed regulations provided that the total UBTI of an exempt organization with more than one unrelated trade or business is the sum of the UBTI with respect to each separate unrelated trade or business, less the specific deduction under section 512(b)(12), and that the UBTI with respect to any separate unrelated trade or business cannot be less than zero.

Section 512(b)(10) and (11) permit exempt organizations to take a charitable contribution deduction. The amount of this deduction, in the case of section 512(b)(10), which applies to most exempt organizations, is limited to 10 percent of UBTI computed without application of the charitable contribution deduction and, in the case of section 512(b)(11), which applies to certain trusts, is limited to the amounts described in section 170(b)(1)(A) and (B) determined with reference to UBTI, again, computed without application of the charitable contribution deduction. The proposed regulations clarified that the term ''unrelated business taxable income'' as used in section 512(b)(10) and (11) refers to UBTI after application of section 512(a)(6). As a result, the limitations on the charitable contribution deduction would be computed using total UBTI under section 512(a)(6)(B).

Although the proposed regulations clarified how to calculate the limitation on the charitable contribution deduction (that is, using total UBTI), the proposed regulations did not explicitly state, other than in the preamble, that the charitable contribution deduction was to be taken against total UBTI. Accordingly, the final regulations have been revised to clarify that the total UBTI of an exempt organization with more than one unrelated trade or business is the sum of the UBTI with respect to each separate unrelated trade or business, less a charitable contribution deduction, an NOL deduction for losses arising in taxable years beginning before January 1, 2018 (discussed in part 6 of this Summary of Comments and Explanation of Revisions), and a specific deduction under section 512(b)(12), as applicable.

One commenter asserted that certain expenses, such as tax return preparation fees and state taxes, are difficult to allocate between two or more unrelated trades or businesses and recommended that exempt organizations be permitted to deduct such expenses against total UBTI. Similarly, this commenter recommended that investment management fees be deducted against total investment related UBTI (instead of total UBTI). In support of this suggestion, this commenter noted that the proposed regulations permitted the charitable contribution deduction in section 512(b)(10) and (11) to be taken against total UBTI.

The final regulations do not adopt this commenter's recommendations. First, the charitable contribution deduction in section 512(b)(10) and (11) is distinguishable from other deductions under section 512(a)(1) or (3) or section 512(b) because the Code specifically provides that this deduction is permitted ''whether or not directly connected with the carrying on of an unrelated trade or business.'' Accordingly, the Treasury Department and the IRS determined that the charitable contribution deduction could be taken against total UBTI calculated under section 512(a)(6)(B).

Second, the structure of section 512(a)(6) itself confirms that Congress did not intend for any deductions to be taken against total UBTI calculated under section 512(a)(6)(B) other than the ones specifically permitted. Section 512(a)(6)(A) provides that, when calculating the UBTI of a separate unrelated trade or business, such calculation is made ''without regard to'' the specific deduction in section 512(b)(12). Section 512(a)(6)(B) clarifies that total UBTI is the sum of UBTI computed with respect to each separate unrelated trade or business ''less a specific deduction under [section] 512(b)(12).'' Thus, the only deductions permitted against total UBTI are a charitable contribution deduction under section 512(b)(10) and (11), an NOL deduction for losses arising in taxable years beginning before January 1, 2018 (permitted by section 13702(b)(2) of the TCJA), and a specific deduction under section 512(b)(12). All other deductions are taken against the UBTI of each separate unrelated trade or business, provided that each such deduction meets the requirements of section 512(a)(1) or (3), as applicable. Any deduction attributable to more than one unrelated trade or business must be allocated in accordance with § 1.512(a)–1(c) of the current regulations.

6. NOLs and UBTI

a. NOL Deduction Calculated Separately With Respect to Each Trade or Business

Consistent with the statute and the proposed regulations, the final regulations provide that, for taxable years beginning after December 31, 2017, an exempt organization with more than one unrelated trade or business determines the NOL deduction allowed by sections 172(a) and 512(b)(6) separately with respect to each of its unrelated trades or businesses. Also consistent with the proposed regulations, the final regulations provide that § 1.512(b)–1(e), which addresses the application of section 172 in the context of UBIT, applies separately with respect to each such unrelated trade or business.

b. Coordination of NOLs

The proposed regulations provided that an organization with losses arising in a taxable year beginning before January 1, 2018 (pre-2018 NOLs), and losses arising in a taxable year beginning after December 31, 2017 (post-2017 NOLs), deducts its pre-2018 NOLs from total UBTI before deducting any post-2017 NOLs with regard to a separate unrelated trade or business against the UBTI from such trade or business. One commenter recommended that an exempt organization be permitted to choose the order in which it uses pre-2018 and post-2017 NOLs based on its own facts and circumstances.

The Treasury Department and the IRS do not accept this recommendation. Section 1.172–4(a)(3) of the current regulations provides that the amount which is carried back or carried over to any taxable year is an NOL ''to the extent it was not absorbed in the computation of the taxable (or net) income for other taxable years, preceding such taxable year, to which it may be carried back or carried over.'' This section further provides that, for the purpose of determining the taxable (or net) income for any such preceding taxable year, the various NOL carryovers and carrybacks to such taxable year are considered to be applied in reduction of the taxable (or net) income in the order of the taxable years from which such losses are carried over or carried back, beginning with the loss for the earliest taxable year. Furthermore, in Notice 2018–67, the Treasury Department and

the IRS noted that section 512(a)(6) may have changed the order in which NOLs are taken and requested comments regarding how the NOL deduction should be taken under section 512(a)(6) by exempt organizations with more than one unrelated trade or business and, in particular, by such organizations with both pre-2018 and post-2017 NOLs. Comments received in response to Notice 2018–67 noted that section 512(a)(6) does not alter the ordering rules under section 172 and that pre-2018 NOLs should be allowed prior to post-2017 NOLs, especially because pre-2018 NOLs remain subject to a carry-forward limitation. The commenter on the proposed regulations provided no new information that would support changing the NOL ordering rule for purposes of section 512(a)(6). Accordingly, the final regulations adopt the proposed regulations without change.

The proposed regulations further provided that pre-2018 NOLs are taken against total UBTI in the manner that results in maximum utilization of the pre-2018 NOLs in a taxable year. One commenter requested that the final regulations clarify the methodology or principle that should be used to allocate pre-2018 NOLs among separate unrelated trades or businesses. The methods suggested by this commenter would result in the pro-rata distribution of pre-2018 NOLs based on various factors, such as the ratio of UBTI of a separate unrelated trade or business to total UBTI. In the alternative, two commenters proposed that an exempt organization be permitted to use any reasonable method to allocate its pre-2018 NOLs.

Although pre-2018 NOLs are taken against total UBTI, pre-2018 NOLs must be allocated in some manner between separate unrelated trades or businesses to determine the amount of pre-2018 NOLs actually taken in a taxable year because the UBTI with respect to each separate unrelated trade or business is calculated before total UBTI and post-2017 NOLs are taken against the UBTI of the separate unrelated trade or business in which they arose. Pre-2018 NOLs could be allocated any number of ways, including ratably between separate unrelated trades or businesses or only to those separate unrelated trades or businesses with no post-2017 NOLs. In permitting the ''maximum utilization of the pre-2018 NOLs in a taxable year'' in the proposed regulations, the Treasury Department and the IRS intended to provide exempt organizations with the flexibility to choose how to allocate pre-2018 NOLs among separate unrelated trades or businesses. However, the actual effect of this rule is to permit an exempt organization to maximize post-2017 NOLs taken against the UBTI from the separate unrelated trades or businesses after taking the pre-2018 NOLs. Accordingly, the final regulations clarify that pre-2018 NOLs are taken against the total UBTI in a manner that allows for maximum utilization of post-2017 NOLs, rather than pre-2018 NOLs, in a taxable year. For example, the final regulations further clarify that an exempt organization may allocate all of its pre-2018 NOLs to one of its separate unrelated trades or businesses or it may allocate its pre-2018 NOLs ratably among its separate unrelated trades or businesses, whichever results in the greater utilization of the post-2017 NOLs in that taxable year.

Additionally, several commenters requested guidance regarding how changes made to section 172 by the Coronavirus Aid, Relief, and Economic Security Act, Public Law 116–136, 134 Stat. 281 (2020) (CARES Act) would affect section 512(a)(6). The Treasury Department and the IRS are considering how these changes affect the calculation of UBTI under section 512(a)(6) and expect to publish additional guidance on the issue. It is anticipated that this additional guidance will include examples that illustrate both how the changes to the CARES Act affect the calculation of UBTI as well as how an exempt organization calculates UBTI when it has pre-2018 NOLs, either with or without post-2017 NOLs.

c. Treatment of NOLs Upon Sale, Transfer, Termination, or Other Disposition of a Separate Unrelated Trade or Business

Several commenters requested guidance on the treatment of accumulated NOLs upon the sale, transfer, termination, or other disposition of a separate unrelated trade or business. At least one commenter recommended that, in such an event, the use of all such prior losses be applied first to any gain realized on the disposition of the trade or business and that any remaining losses be permitted to offset UBTI from other, separate unrelated trades or businesses. Another commenter recommended that any accumulated NOLs be suspended and taken if the exempt organization later resumes the separate unrelated trade or business.

Section 512(a)(6) permits only pre-2018 NOLs to be taken against total UBTI. Consistent with the legislative intent of section 512(a)(6), losses attributable to a separate unrelated trade or business may be taken only against income from that separate unrelated trade or business. However, the Treasury Department and the IRS recognize that an exempt organization later may recommence that separate unrelated trade or business or acquire a separate unrelated trade or business identified in the same manner. Accordingly, the final regulations provide that, after offsetting any gain from the termination, sale, exchange, or other disposition of a separate unrelated trade or business, any NOL remaining is suspended. However, the suspended NOLs may be used if that previous separate unrelated trade or business is later resumed or if a new unrelated trade or business that is accurately identified using the same NAICS 2-digit code as the previous separate unrelated trade or business is commenced or acquired in a future taxable year.

d. Treatment of NOLs Upon Changing Identification of a Separate Unrelated Trade or Business

Six commenters requested that the final regulations clarify what happens to NOLs when a partnership interest moves in and out of QPI status. The Treasury Department and the IRS expect that the grace period described in part 2.b.vi of this Summary of Comments and Explanation of Revisions will reduce the incidence of partnership interests moving in and out of QPI status. Nonetheless, instances will exist where a partnership interest that was a QPI becomes a non-QPI. Additionally, as discussed in part 1.d of this Summary of Comments and Explanation of Revisions, an exempt organization may change the NAICS 2-digit code identifying a separate unrelated trade or business. Thus, the same question exists regarding what happens to NOLs when the NAICS 2-digit code identifying a separate unrelated trade or business changes.

In response to the commenters, the final regulations generally provide that, for purposes of section 512(a)(6), a separate unrelated trade or business that changes identification is treated as if the originally identified separate unrelated trade or business is terminated and a new separate unrelated trade or business is commenced. As a result, none of the NOLs from the previously identified separate unrelated trade or business will be carried over to the newly identified separate unrelated trade or business. For example, if the nature of a separate unrelated trade or business changes such that it is more accurately described by another NAICS 2-digit code, the separate unrelated trade or business is treated as a new

separate unrelated trade or business with no NOLs.

The final regulations further clarify that the change in identification may apply to all or a part of the originally identified separate unrelated trade or business. If the change in identification applies to the originally identified separate trade or business in its entirety, any NOLs attributable to that separate unrelated trade or business are suspended. If the change in identification applies to the originally identified separate unrelated trade or business in part, to aid in tax administration and to avoid a need for allocation of NOLs within an originally identified separate trade or business, the originally identified separate unrelated trade or business that is not changing retains the full NOLs attributable to it, including the portion for which the identification is changing. Additionally, the final regulations provide that this general rule also applies to the separate unrelated trades or businesses that are identified when a QPI becomes a non-QPI. In this case, any NOLs attributable to the QPI that became a non-QPI are retained with the organization's investment activities.

Under the final regulations, a change in identification is effective as of the first day of the taxable year in which the change is made. Accordingly, the final regulations treat the newly identified separate unrelated trade or business as commencing on this date.

Nonetheless, the final regulations provide an exception for when an organization has determined that an unrelated trade or business is more accurately identified by another NAICS 2-digit code, provided that there has been no material change in the unrelated trade or business. In these cases, the final regulations provide that the NOLs attributable to the previously identified separate unrelated trade or business are NOLs of the newly identified separate unrelated trade or business. This approach is consistent with the legislative intent that losses from one unrelated trade or business not be used to offset the gains from another unrelated trade or business but recognizes that mistakes may be made and that NOLs should not be suspended (as discussed in part 6.c of this Summary of Comments and Explanation of Revisions) in such a case. The final regulations provide examples illustrating the application of these rules regarding NOLs.

e. Coordination of NOL and Excess Charitable Contribution Carryovers

The proposed regulations requested comments on the coordination of NOL and excess contribution carryovers. The proposed regulations noted that an ordering rule may be necessary. Although a few comments were received, these final regulations do not address this issue. The Treasury Department and the IRS continue to consider this issue and will issue additional guidance, if needed.

7. Form 990–T

At least one commenter requested clarification regarding the reporting of separate unrelated trades or businesses that do not have corresponding NAICS codes, such as investment activities, income from certain controlled entities, and non-qualifying S corporation interests. The IRS is in the process of revising the 2020 Form 990–T and related instructions. It is anticipated that separate unrelated trades or businesses that are not identified using NAICS 2-digit codes—that is, separate unrelated trades or businesses identified under § 1.512(a)–6(c) (investment activities), (d)(1) (specified payments from controlled entities), (d)(2) (certain amounts derived from controlled foreign corporations), and (e) (non-qualifying S corporation interests)—will be identified using numeric codes distinguishable from NAICS codes. The instructions to the Form 990–T will explain how an exempt organization determines the appropriate code to use, as well as how to report code changes.

8. Waiver of Penalties Not Provided

One commenter requested that the Treasury Department and the IRS waive any penalties arising from the underpayment of tax for tax years prior to the applicability date of the final regulations. As discussed in the Applicability Dates section of this preamble, an exempt organization may rely on a reasonable, good-faith interpretation of section 512(a)(6) prior to the applicability date of the final regulations. Accordingly, the Treasury Department and the IRS decline to waive any underpayment penalties with respect to the calculation of UBTI under section 512(a)(6).

9. Individual Retirement Accounts

The proposed regulations added a new paragraph to § 1.513–1 clarifying that the section 513(b) definition of ''unrelated trade or business'' applies to individual retirement accounts (IRAs) described in section 408. No comments were received with respect to this provision. Accordingly, the final regulations adopt these proposed regulations without change.

10. Inclusions of Subpart F Income and Global Intangible Low-Taxed Income

The proposed regulations revised § 1.512(b)–1(a) to clarify that an inclusion of subpart F income under section 951(a)(1)(A) is treated in the same manner as a dividend for purposes of section 512(b)(1) and that an inclusion of global intangible low-taxed income (GILTI) under section 951A(a) is treated in the same manner as an inclusion of subpart F income under section 951(a)(1)(A) for purposes of section 512(b)(1). At least one commenter explicitly supported this treatment of an inclusion of subpart F income or GILTI and no other comments were received. Therefore, the final regulations adopt these proposed regulations without change.

11. Public Support

The preamble to the proposed regulations confirmed that section 512(a)(6) potentially impacted the calculation of public support under sections 509(a)(1) and 170(b)(1)(A)(vi) and under section 509(a)(2) (the public support tests) because of the inability of an exempt organization with more than one unrelated trade or business to use losses from one unrelated trade or business to offset gains from another unrelated trade or business. Furthermore, the preamble to the proposed regulations noted that the Treasury Department and the IRS were not aware of any congressional intent to change the public support tests in enacting section 512(a)(6). Accordingly, the proposed regulations revised §§ 1.170A–9(f) and 1.509(a)–3 to permit an organization with more than one unrelated trade or business to aggregate its net income and net losses from all of its unrelated business activities, including unrelated trades or businesses within the meaning of section 512, for purposes of determining whether an organization is publicly supported.

Commenters agreed that Congress likely did not intend to change the public support tests when enacting section 512(a)(6) and generally supported the proposed clarifications to the public support test. However, two commenters noted that an exempt organization that satisfies the public support tests using its UBTI calculated for purposes of section 512(a)(6) also will satisfy the public support tests if it calculates its UBTI in the aggregate. These commenters therefore recommended that an exempt organization be permitted to use either its UBTI calculated under section 512(a)(6) or its UBTI calculated in the aggregate to determine public support.

These commenters noted that this approach would reduce the administrative burden on exempt organizations because organizations that satisfy the requirements of the public support test using their UBTI calculated under section 512(a)(6) would not be required to recalculate UBTI in the aggregate. At the same time, this approach would also address any unintended consequence of the enactment of section 512(a)(6) for exempt organizations that have historically satisfied the requirements of the public support test but would no longer because of the effect of section 512(a)(6). The final regulations adopt these commenters' suggestions and permit an exempt organization with more than one unrelated trade or business to determine public support using either its UBTI calculated under section 512(a)(6) or its UBTI calculated in the aggregate.

12. Technical Correction of Inadvertently Omitted Regulatory Language

The proposed regulations made a technical correction to § 1.512(a)–1(b) by including language that was omitted from the **Federal Register** when the final regulation was published in 1975. No comments were received with respect to this technical correction. Accordingly, the final regulations adopt the technical correction in the proposed regulations without change.

Applicability Dates

The proposed regulations were proposed to apply to taxable years beginning on or after the date the regulations were published in the **Federal Register** as final regulations. Two commenters recommended that the applicability date of the final regulations be delayed. Another commenter suggested that the applicability date be extended such that all exempt organizations be provided with at least one year before the final regulations are applicable. This commenter explained that time will be required to implement the final regulations, including making changes to accounting systems. Accordingly, this commenter proposed that the applicability date of the final regulations be extended to the first day of the second taxable year beginning after the date the final regulations are published in the **Federal Register**.

The Treasury Department and the IRS recognize that implementation of the requirements of section 512(a)(6) by some exempt organizations requires changes to the way these organizations track income and expenses. However, the Treasury Department and the IRS have provided guidance regarding how exempt organizations would be expected to comply with section 512(a)(6) starting with Notice 2018–67 in September of 2018 and continuing with the proposed regulations in April of 2020. The final regulations adopt the proposed regulations with minor changes requested by commenters. Accordingly, consistent with the proposed regulations, the final regulations are applicable to taxable years beginning on or after December 2, 2020. In addition, an exempt organization may choose to apply the final regulations under section 512(a)(6), as well as the final regulations relating to the calculation of public support, to taxable years beginning on or after January 1, 2018, and before December 2, 2020. Alternatively, an exempt organization may rely on a reasonable, good-faith interpretation of section 512(a)(6) for such taxable years. For this purpose, a reasonable good faith interpretation includes the methods of aggregating or identifying separate trades or businesses provided in Notice 2018–67 or the proposed regulations.

With respect to the inclusions of subpart F income or GILTI discussed in part 10 of the Summary of Comments and Explanation of Revisions, a taxpayer may choose to apply the final regulations under § 1.512(b)–1(a) to taxable years beginning before December 2, 2020 consistent with the longstanding position of the Treasury Department and the IRS on the inclusion of subpart F income under section 951(a)(1)(A).

Statement of Availability of IRS Documents

For copies of recently issued Revenue Procedures, Revenue Rulings, Notices, and other guidance published in the Internal Revenue Bulletin, please visit the IRS website at *http://www.irs.gov* or the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Executive Orders 12866, 13563, and 13771 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

These final regulations have been designated as significant and subject to review under Executive Order 12866 and section 1(b) of the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations. For purposes of Executive Order 13771, the final regulations are regulatory. The Administrator of the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, has waived review of this rule in accordance with section 6(a)(3)(A) of Executive Order 12866.

1. Background

Certain corporations, trusts, and other entities are exempt from Federal income taxation because of the specific functions they perform (exempt organizations). Examples include religious and charitable organizations. However, exempt organizations that engage in business activities that are not substantially related to their exempt purposes may have taxable income under section 511(a)(1) of the Internal Revenue Code (Code). For example, the income that a tax-exempt organization generates from the sale of advertising in its quarterly magazine is unrelated business taxable income (UBTI).

Prior to the Tax Cuts and Jobs Act (TCJA), UBTI was calculated by aggregating the net incomes from all the unrelated business activities conducted by an exempt organization. As a result, losses from one unrelated trade or business activity could be used to offset profits from another unrelated trade or business activity. New section 512(a)(6), enacted in the TCJA, provides that organizations with more than one unrelated trade or business calculate the taxable amounts separately for each trade or business so that losses only offset income from the same unrelated trade or business. The statutory language, however, does not specify standards for determining what activities would be considered the same or a different trade or business.

On April 21, 2020, the Department of the Treasury (Treasury Department) and the IRS published a notice of proposed rulemaking (REG–106864–18) in the **Federal Register** (85 FR 23172) containing proposed regulations under section 512 (proposed regulations). The final regulations retain the basic approach and structure of the proposed regulations with certain minor modifications. As part of these modifications, the final regulations

modify the participation test (called the ''control test'' in the proposed regulations) to permit indirectly held partnerships interests to be eligible for inclusion in an exempt organization's single ''investment activities'' trade or business. The final regulations address the need for guidance by providing rules for determining when an exempt organization has more than one unrelated trade or business and how such an exempt organization computes UBTI under new section 512(a)(6). Specifically discussed below, the final regulations establish guidelines for (1) identifying separate unrelated trades or businesses; and (2) in certain cases, permitting an exempt organization to treat investment activities as one unrelated trade or business for purposes of computing UBTI.

2. Baseline

In this analysis, the Treasury Department and the IRS assess the benefits and costs of these proposed regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these proposed regulations.

3. Affected Entities

Prior tax law did not require tax-exempt organizations to report unrelated business income by separate activity, so it is not possible to obtain accurate counts of the number of exempt organizations potentially affected by the final regulations. However, the IRS estimates that less than 2 percent of exempt organizations would be affected, as calculated below.

Approximately 1.4 million exempt organizations filed some type of information or tax return with the IRS for fiscal year 2018.[7] Only 188,000 exempt organizations filed Form 990–T, which is used to report UBTI. While not all Form 990–T filers also file an information return with the IRS, as an upper bound estimate, 14 percent of exempt organizations could be affected by the regulations. Within Form 990–T filers, only a smaller subset, primarily the largest organizations in certain categories, are expected to have more than one unrelated trade or business. Among the types of organizations expected to have more than one unrelated trade or business are colleges and universities, certain cultural organizations such as museums, and some tax-exempt hospitals.

Additional information on organizations that may be affected is provided by a 2018 Center on Nonprofits and Philanthropy (CNP) survey of 723 primarily large exempt organizations.[8] Three-hundred and thirty of these organizations reported that they had filed a Form 990–T. Of these, 70 percent had revenues over $10 million and most were educational or arts and cultural organizations. Only 46 organizations (14 percent of the surveyed organizations filing Form 990–T) reported having more than one source of UBTI and almost half of these had only two sources. Thus, the Treasury Department and the IRS project that if the CNP survey results applied to the population of Form 990–T filers, then less than 2 percent of exempt organizations or approximately 4,000 filers would be affected by the final regulations and that these would tend to be large educational or arts and cultural organizations.

4. Economic Analysis of Final Regulations

The final regulations provide greater certainty to exempt organizations regarding how to compute UBTI and tax in response to the changes made by TCJA. They also improve economic efficiency by helping to ensure that similar exempt organizations are taxed similarly. In the absence of this guidance taxpayers might make different assumptions regarding how to calculate UBTI and tax.

This section describes the two major provisions of the final rule and provides a qualitative economic analysis of each one.

a. Identifying Separate Trades or Businesses

Section 512(a)(6) requires exempt organizations with more than one unrelated trade or business to calculate UBTI separately for each trade or business so that losses are used to offset only income from the same unrelated trade or business. The final regulations generally require the use of NAICS codes to identify separate unrelated trades or businesses. NAICS is an industry classification system for purposes of collecting, analyzing, and publishing statistical data related to the United States business economy. Each digit of the NAICS 6-digit codes describes an industry with increasing specificity. The final regulations allow the use of NAICS 2-digit codes, which encompass broader categories of trades or businesses than NAICS 6-digit codes, to reduce the compliance burdens for exempt organizations with multiple similar types of business activity. For example, different types of food services would be included in the same NAICS 2-digit code as opposed to separate NAICS 6-digit codes. Similarly, different types of recreational activities, such as fitness centers and golf courses, would be in the same NAICS 2-digit code as opposed to separate NAICS 6-digit codes. A single facility might have elements fitting several of these categories, which could change over time when NAICS codes are revised. The use of NAICS 6-digit codes could potentially require an exempt organization to split what has traditionally been considered one unrelated trade or business into multiple unrelated trades or businesses. In addition, exempt organizations may need to incur the costs of changing their accounting systems so as to collect the information needed for separate NAICS 6-digit codes.

Some commenters to the proposed regulations advocated using the NAICS 2-digit codes as a safe-harbor when identifying separate unrelated trades or businesses and that a facts and circumstances test be applied as the primary method of identifying separate unrelated businesses. Adoption of a facts and circumstances test would increase the administrative burden of tax-exempt organizations in complying with section 512(a)(6) because fact-intensive analysis would be required to determine each unrelated trade or business. Additionally, adoption of a facts and circumstances test would offer exempt organizations less certainty and increase the IRS administrative burden.

The guidance provided in the final regulations ensures that the tax liability is calculated similarly across taxpayers, avoiding situations where one taxpayer receives differential treatment compared to another taxpayer for fundamentally similar economic activity based on their differing reasonable, good-faith interpretations of the statute. In the absence of these final regulations, an exempt organization might be uncertain about whether an activity is one or more than one trade or business. As a result, in the absence of the final regulations, similar institutions might take different positions and pay different amounts of tax, introducing economic inefficiency and inequity. These regulations provide

[7] *See* Internal Revenue Service Research, Applied Analytics, and Statistics, Statistics of Income Division Fiscal Year Return Projections for the United States Publication 6292 (Rev. 9–2019), Projected Returns 2019–2026. Exempt organizations generally must file an annual information return with IRS. *See generally* section 6033. However, churches and small organizations are exempt from this filing requirement. *See* section 6033(a)(3). Organizations that have more than $1,000 in gross UBTI must also file Form 990–T to calculate their UBTI and tax. *See* section 512(b)(12) (providing a $1,000 specific deduction).

[8] *See* Elizabeth Boris and Joseph Cordes, ''How the TCJA's New UBIT Provisions Will Affect Nonprofits,'' Urban Institute Research Report, January 2019.

greater certainty and flexibility such that compliance costs may be slightly lower for affected organizations relative to a no-action baseline.

b. Aggregation of Investment Activities

The final regulation's treatment of investment activities will also provide clarity and reduce burdens for exempt organizations. By providing explicit rules for the treatment of investment activities, the final regulations reduce the uncertainty about what would be acceptable under a reasonable, good-faith interpretation. Although investment income, such as interest and dividend income, is not generally statutorily taxed as UBTI, exempt organizations may engage in certain activities that the organization considers ''investments'' but that generate UBTI, such as debt-financed investments or investments through partnerships. The final regulations allow certain of this investment income to be aggregated and treated as a single trade or business. The final regulations provide rules for the treatment of partnership income and explicitly list the other types of UBTI that can be aggregated as ''investment'' income in response to comments requesting additional clarification. The allowance of this type of aggregation is responsive to situations where exempt organizations are invested in partnerships in which they do not significantly participate. The allowance of aggregation in the final regulations recognizes that in these situations the exempt organizations are unlikely to be able to access information from such partnerships for purposes of separating the partnerships' investments according to NAICS codes. As a result, the final regulations reduce the compliance burdens of exempt organizations of obtaining information from partnerships and simplify the calculation of UBTI when the income is generated from ''investment'' activities relative to the no-action baseline.

c. Summary

The final regulations provide rules for determining when an exempt organization has more than one unrelated trade or business and how such an exempt organization computes UBTI. In addition, the final regulations provide guidelines for when an exempt organization treats its investment activities as one unrelated trade or business for purposes of computing UBTI. In the absence of guidance, affected taxpayers may face more uncertainty when calculating their tax liability, a situation generally that could lead to greater conflicts with tax administrators. The Treasury Department and the IRS project that the final regulations will reduce taxpayer compliance burden relative to the no-action baseline. In addition, the Treasury Department and the IRS project that these regulations will affect a small number of exempt organizations. Based on this analysis, the Treasury Department and the IRS anticipate any economic effects of the final regulations will be modest relative to the no-action baseline.

II. Paperwork Reduction Act

The collections of information contained in the final regulations will be submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of (1995) (44 U.S.C. 3507(d)). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and return information are confidential, as required by 26 U.S.C. 6103.

1. Collections of Information Imposed by the Regulations

The collection of information in these final regulations is in § 1.512(b)–6(a). This information is required to determine whether an exempt organization has more than one unrelated trade or business and therefore must report those unrelated trades or businesses on Form 990–T and related schedules. In 2018, the IRS released and invited comments on drafts of an earlier version of the Form 990–T and related schedules to give members of the public opportunity to comment on changes made to the Form 990–T, and the addition of a new schedule to report additional unrelated trades or businesses, as required by the enactment of section 512(a)(6). The IRS received no comments on the Form 990–T and related schedules during that comment period. Consequently, the IRS made Form 990–T available on January 8, 2019, and the new schedule for reporting additional unrelated trades or businesses available on January 25, 2019, for use by the public. The IRS intends that the burden of collections of information will be reflected in the burden associated with the Form 990 series under OMB approval number 1545–0047.

2. Burden Estimates

The burden associated with Form 990–T is included in the aggregated burden estimates for OMB control number 1545–0047. The burden estimates in 1545–0047 relate to all filers associated with the Forms 990, and will in the future include, but not isolate, the estimated burden of the information collections associated with these final regulations.

No burden estimates specific to the final regulations are currently available. The Treasury Department has not estimated the burden, including that of any new information collections, related to the requirements under the final regulations. Those estimates would capture both changes made by the Act and those that arise out of discretionary authority exercised in the final regulations. The current status of the Paperwork Reduction Act submissions related to these final regulations is provided in the following table.

Form	OMB control No.	Status
990 and related forms	1545–0047	Sixty-day notice published on 9/24/2019. Thirty-day notice published on 12/31/2019. Approved by OIRA on 2/12/2020.
	Link: *https://www.irs.gov/forms-pubs/about-form-990.*	

In the proposed regulations, the Treasury Department and the IRS requested comments on all aspects of information collection burdens related to the regulations, including estimates for how much time it would take to comply with the paperwork burdens described above for each relevant form and ways for the IRS to minimize the paperwork burden. The Treasury Department and the IRS did not receive any comments on these issues. Proposed

revisions (if any) to the forms that reflect the information collections contained in these final regulations will be made available for public comment at *https://apps.irs.gov/app/picklist/list/draftTaxForms.html* and will not be finalized until after these forms have been approved by OMB under the PRA. Comments on these forms can be submitted at *https://www.irs.gov/forms-pubs/comment-on-tax-forms-and-publications*.

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these final regulations will not have a significant economic impact on a substantial number of small entities. In the proposed regulations, the Treasury Department and the IRS invited comments on the impact this rule may have on small entities. The Treasury Department and the IRS did not receive any comments on this issue. As discussed elsewhere in this section, these final regulations apply to all exempt organizations with UBTI, but only to the extent required to determine if an exempt organization has more than one unrelated trade or business. If an exempt organization only has one unrelated trade or business, these regulations do not apply and the exempt organization determines UBTI under section 512(a)(1) or section 512(a)(3), as appropriate. If an exempt organization has more than one unrelated trade or business, these proposed regulations provide instructions for computing UBTI separately with respect to each such unrelated trade or business.

These final regulations are not likely to affect a substantial number of small entities. According to the IRS Data Book, 1,835,534 exempt organizations existed in 2018. Internal Revenue Service, Publication 55B, Internal Revenue Service Data Book 2018, 57 (May 2019). However, only 188,334 Form 990-Ts were filed in 2018. Internal Revenue Service, Publication 6292, Fiscal Year Return Projects for the United States: 2019–2026, Fall 2019 4 (September 2019). Accordingly, approximately 10 percent of the exempt organization population file Form 990–T. This population includes large hospital systems and universities not included in the SBA definition of ''small entities.'' Therefore, these final regulations are not likely to affect a substantial number of small entities.

Even if the regulations affected a substantial number of small entities, the economic impact of these final rules are not likely to be significant. An organization affected by this rule, with more than one unrelated trade or business, completes Part I and Part II on page 1 of Form 990–T and completes and attaches a separate schedule for each additional unrelated trade or business. Affected taxpayers have been reporting UBTI on form 990–T for separate unrelated trades or businesses for the previous two tax years. As discussed elsewhere in this section, these regulations provide certainty and guidance for these organizations. In the absence of this guidance, affected taxpayers may face more uncertainty when calculating their tax liability, a situation generally that could lead to greater conflicts with tax administrators. Although affected taxpayers will have to spend time reading these final regulations, the Treasury Department and the IRS project that the final regulations provide certainty and guidance that will reduce taxpayer compliance burden for large and small entity taxpayers. Accordingly, the Secretary of the Treasury's delegate certifies that these regulations will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f), the notice of proposed rulemaking was submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business (84 FR 31795). No comments on the notice were received from the Chief Counsel for the Office of Advocacy of the Small Business Administration.

IV. Congressional Review Act

The Office of Management and Budget has determined that the final rule is not a ''major rule'' within the meaning of the Congressional Review Act (5 U.S.C. 801, *et seq.*).

V. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. The final regulations do not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

VII. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. The final regulations do not have federalism implications and do not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

Drafting Information

The principal authors of these regulations are Stephanie N. Robbins and Jonathan A. Carter, Office of the Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 are amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.170A–9 is amended by:

■ 1. Adding paragraph (f)(7)(v).

■ 2. Adding paragraph (k)(3).

The additions read as follows:

§ 1.170A–9 Definition of section 170(b)(1)(A) organization.

* * * * *

(f) * * *

(7) * * *

(v) *Unrelated business activities.* The term *net income from unrelated business activities* in section 509(d)(3) includes (but is not limited to) an organization's unrelated business taxable income (UBTI) within the meaning of section 512. However, when calculating UBTI for purposes of determining support (within the meaning of this paragraph (f)(7)), section 512(a)(6) does not apply. Accordingly, in the case of an organization that derives gross income from the regular conduct of two or more unrelated business activities, support includes the aggregate of gross income from all such unrelated business activities less the aggregate of the deductions allowed with respect to all such unrelated business activities. Nonetheless, when

determining support, such organization can use either its UBTI calculated under section 512(a)(6) or its UBTI calculated in the aggregate.

* * * * *

(k) * * *

(3) *Applicability date.* Paragraph (f)(7)(v) of this section applies to taxable years beginning on or after December 2, 2020. Taxpayers may choose to apply this section to taxable years beginning on or after January 1, 2018, and before December 2, 2020.

■ **Par. 3.** Section 1.509(a)–3 is amended by:

■ 1. Revising the first sentence of paragraph (a)(3)(i).

■ 2. Redesignating paragraph (a)(4) as paragraph (a)(5).

■ 3. Adding new paragraph (a)(4).

■ 4. Revising paragraph (o).

The revisions and additions read as follows:

§ 1.509(a)–3 Broadly, publicly supported organizations.

(a) * * *

(3) * * *

(i) * * * An organization will meet the not-more-than-one-third support test under section 509(a)(2)(B) if it normally (within the meaning of paragraph (c) or (d) of this section) receives not more than one-third of its support in each taxable year from the sum of its gross investment income (as defined in section 509(e)) and the excess (if any) of the amount of its unrelated business taxable income (as defined in section 512, without regard to section 512(a)(6), or with regard to section 512(a)(6), if the organization so chooses) derived from trades or businesses that were acquired by the organization after June 30, 1975, over the amount of tax imposed on such income by section 511.

* * * * *

(4) *Unrelated business activities.* The denominator of the one-third support fraction and the denominator of the not-more-than-one-third support fraction both include net income from unrelated business activities, whether or not such activities are carried on regularly as a trade or business. The term *net income from unrelated business activities* includes (but is not limited to) an organization's unrelated business taxable income (UBTI) within the meaning of section 512. However, when calculating UBTI for purposes of determining the denominator of both support fractions, section 512(a)(6) does not apply. Accordingly, in the case of an organization that derives gross income from the regular conduct of two or more unrelated business activities, support includes the aggregate of gross income from all such unrelated business activities less the aggregate of the deductions allowed with respect to all such unrelated business activities. Nonetheless, when determining support, such organization can use either its UBTI calculated under section 512(a)(6) or its UBTI calculated in the aggregate.

* * * * *

(o) *Applicability date.* This section generally applies to taxable years beginning after December 31, 1969, except paragraphs (a)(3)(i) and (a)(4) of this section apply to taxable years beginning on or after December 2, 2020. Taxpayers may choose to apply this section to taxable years beginning on or after January 1, 2018, and before December 2, 2020. Otherwise, for taxable years beginning before December 2, 2020, see these paragraphs as in effect and contained in 26 CFR part 1 revised as of April 1, 2020.

■ **Par. 4.** Section 1.512(a)–1 is amended by:

■ 1. Revising the first and fourth sentence of paragraph (a).

■ 2. Revising the first and second sentence of paragraph (b).

■ 3. Adding two sentences to the end of paragraph (c).

■ 4. Revising paragraph (h).

The revisions and additions read as follows:

§ 1.512(a)–1 Definition.

(a) * * * Except as otherwise provided in § 1.512(a)–3, § 1.512(a)–4, or paragraph (f) of this section, section 512(a)(1) defines *unrelated business taxable income* as the gross income derived from any unrelated trade or business regularly carried on, less those deductions allowed by chapter 1 of the Internal Revenue Code (Code) which are directly connected with the carrying on of such trade or business, subject to certain modifications referred to in § 1.512(b)–1. * * * In the case of an organization with more than one unrelated trade or business, unrelated business taxable income is calculated separately with respect to each such trade or business. *See* § 1.512(a)–6.

* * *

(b) * * * Expenses, depreciation, and similar items attributable solely to the conduct of unrelated business activities are proximately and primarily related to that business activity, and therefore qualify for deduction to the extent that they meet the requirements of section 162, section 167, or other relevant provisions of the Code. Thus, for example, salaries of personnel employed full-time in carrying on unrelated business activities are directly connected with the conduct of that activity and are deductible in computing unrelated business taxable income if they otherwise qualify for deduction under the requirements of section 162. * * *

(c) * * * However, allocation of expenses, depreciation, and similar items is not reasonable if the cost of providing a good or service in a related and an unrelated activity is substantially the same, but the price charged for that good or service in the unrelated activity is greater than the price charged in the related activity and no adjustment is made to equalize the price difference for purposes of allocating expenses, depreciation, and similar items based on revenue between related and unrelated activities. For example, if a social club described in section 501(c)(7) charges nonmembers a higher price than it charges members for the same good or service but does not adjust the price of the good or service provided to members for purposes of allocating expenses, depreciation, and similar items attributable to the provision of that good or service, the allocation method is not reasonable.

* * * * *

(h) *Applicability date.* This section generally applies to taxable years beginning after December 12, 1967, except as provided in paragraph (g)(2) of this section, and except that paragraphs (a) through (c) of this section apply to taxable years beginning on or after December 2, 2020. For taxable years beginning before December 2, 2020, see these paragraphs as in effect and contained in 26 CFR part 1 revised as of April 1, 2020.

■ **Par. 5.** Section 1.512(a)–6 is added to read as follows:

§ 1.512(a)–6 Special rule for organizations with more than one unrelated trade or business.

(a) *More than one unrelated trade or business*—(1) *In general.* An organization with more than one unrelated trade or business must compute unrelated business taxable income (UBTI) separately with respect to each such trade or business, without regard to the specific deduction in section 512(b)(12), including for purposes of determining any net operating loss (NOL) deduction. An organization with more than one unrelated trade or business computes its total UBTI under paragraph (g) of this section.

(2) *Separate trades or businesses.* An organization determines whether it regularly carries on unrelated trades or businesses by applying sections 511 through 514. For purposes of section

512(a)(6)(A) and paragraph (a)(1) of this section, an organization identifies its separate unrelated trades or businesses using the methods described in paragraphs (b) through (e) of this section.

(3) *Reporting changes in identification.* An organization that changes the identification of a separate unrelated trade or business under paragraph (a)(2) of this section must report the change in the taxable year of that change in accordance with forms and instructions. For this purpose, a change in identification of a separate unrelated trade or business includes the changed identification of the separate unrelated trade or business with respect to a partnership interest that was incorrectly designated as a qualifying partnership interest (QPI). In the case of an incorrect designation of a QPI, paragraph (c)(2)(iii) of this section (regarding designation of qualifying partnership interests) does not apply. In all cases, to report the change in identification, an organization must provide the following information with respect to each separate change in identification—

(i) The identification of the separate unrelated trade or business in the previous taxable year

(ii) The identification of the separate unrelated trade or business in the current taxable year; and

(iii) The reason for the change.

(b) *North American Industry Classification System*—(1) *In general.* Except as provided in paragraphs (c) through (e) of this section, an organization identifies each of its separate unrelated trades or businesses using the first two digits of the North American Industry Classification System code (NAICS 2-digit code) that most accurately describes the unrelated trade or business based on the more specific NAICS code, such as at the 6-digit level, that describes the activity it conducts and subject to the requirements of paragraph (b)(2) and (3) of this section. The descriptions in the current NAICS manual (available at *www.census.gov*) of trades or businesses using more than two digits of the NAICS codes are relevant in this determination. In the case of the sale of goods, both online and in stores, the separate unrelated trade or business is identified by the goods sold in stores if the same goods generally are sold both online and in stores.

(2) *Codes must identify the unrelated trade or business.* The NAICS 2-digit code must identify the unrelated trade or business in which the organization engages (directly or indirectly) and not activities the conduct of which are substantially related to the exercise or performance by such organization of its charitable, educational, or other purpose or function constituting the basis for its exemption under section 501 (or, in the case of an organization described in section 511(a)(2)(B), to the exercise or performance of any purpose or function described in section 501(c)(3)). For example, a college or university described in section 501(c)(3) cannot use the NAICS 2-digit code for educational services to identify all its separate unrelated trades or businesses, and a qualified retirement plan described in section 401(a) cannot use the NAICS 2-digit code for finance and insurance to identify all of its unrelated trades or businesses.

(3) *Codes only reported once.* An organization will report each NAICS 2-digit code only once. For example, a hospital organization that operates several hospital facilities in a geographic area (or multiple geographic areas), all of which include pharmacies that sell goods to the general public, would include all the pharmacies under the NAICS 2-digit code for retail trade, regardless of whether the hospital organization keeps separate books and records for each pharmacy.

(c) *Activities in the nature of investments*—(1) *In general.* An organization's activities in the nature of investments (investment activities) are treated collectively as a separate unrelated trade or business for purposes of section 512(a)(6) and paragraph (a) of this section. Except as provided in paragraphs (c)(7) and (c)(8) of this section, an organization's investment activities are limited to its—

(i) Qualifying partnership interests (described in paragraph (c)(2) of this section);

(ii) Qualifying S corporation interests (described in paragraph (e)(2)(i) of this section); and

(iii) Debt-financed property or properties (within the meaning of section 514).

(2) *Qualifying partnership interests*—(i) *Directly-held partnership interests.* An interest in a partnership is a qualifying partnership interest (QPI) if the exempt organization holds a direct interest in the partnership (directly-held partnership interest) that meets the requirements of either the de minimis test (described in paragraph (c)(3) of this section) or the participation test (described in paragraph (c)(4) of this section).

(ii) *Indirectly-held partnership interests*—(A) *Look through rule.* If an organization holds a direct interest in a partnership but that directly-held partnership interest is not a QPI because it does not meet the requirements of the de minimis test (described in paragraph (c)(3) of this section) or the participation test (described in paragraph (c)(4) of this section), any partnership in which the organization holds an indirect interest through the directly-held partnership interest (indirectly-held partnership interest) may be a QPI if the indirectly-held partnership interest meets the requirements of paragraph (c)(2)(ii)(B) or (c)(2)(ii)(C) of this section.

(B) *Indirectly-held partnership interests that meet the requirements of the de minimis test.* An indirectly-held partnership interest meets the requirements of this paragraph (c)(2)(ii)(B) if the indirectly-held partnership interest meets the requirements of the de minimis test described in paragraph (c)(3) of this section with regard to the organization. For example, if an organization directly holds 50 percent of the capital interests of a partnership and the directly-held partnership holds 4 percent of the capital and profits interest of lower-tier partnership A, the organization may aggregate its interest in lower-tier partnership A with its other QPIs because the organization indirectly holds 2 percent of the capital and profits interests of lower-tier partnership A (4 percent × 50 percent).

(C) *Indirectly-held partnership interests that meet the requirements of the participation test.* An indirectly-held partnership interest meets the requirements of this paragraph (c)(2)(ii)(C) if the indirectly-held partnership interest meets the requirements of the participation test (described in paragraph (c)(4) of this section) with respect to the partnership that directly owns the interest in the indirectly-held partnership. For purposes of applying the participation test to a partnership, the term *organization* in paragraph (c)(4) of this section refers to the partnership that directly holds the indirectly-held partnership interest being tested for QPI status. Additionally, the list of officers, directors, trustees, or employees of an organization found in paragraphs (c)(4)(iii)(B) and (C) includes a general partner that directly owns an interest in the lower-tier partnership.

(D) *Example*—(*1*) Organization D is described in section 501(c) and is exempt from Federal income tax under section 501(a). Organization D owns 50 percent of the capital interest in Partnership A. Partnership A owns 30 percent of the capital interest in Partnership B, but Partnership A does not significantly participate in Partnership B within the meaning of paragraph (c)(4)(iii) of this section.

Further, Partnership B owns 15 percent of the capital interest in Partnership C, in which Partnership B does not significantly participate within the meaning of paragraph (c)(4)(iii) of this section. No other organizations related (within the meaning of paragraph (c)(4)(ii) of this section) to either Organization D or the partnerships owns an interest in any of the lower-tier partnerships.

(*2*) Neither the interest in Partnership A nor B is a QPI. Organization D's interest in Partnership A does not meet the requirements of either the de minimis test or the participation test because it owns 50 percent of the interest in the partnership. Organization D's indirect interest in Partnership B (50 percent of 30 percent, or 15 percent) does not meet the de minimis test. Additionally, because Partnership A owns greater than 20 percent interest in Partnership B, Partnership A's interest in Partnership B does not meet the participation test. However, Organization D's interest in Partnership C is a QPI because Partnership C meets the participation test. That is, Partnership B holds a 15 percent interest in Partnership C and does not significantly participate in Partnership C.

(iii) *Designation.* An organization that has a partnership interest meeting the requirements of paragraph (c)(2)(i) or (ii) of this section in a taxable year may designate that partnership interest as a QPI by including its share of partnership gross income (and directly connected deductions) with the gross income (and directly connected deductions) from its other investment activities (see paragraph (c)(1) of this section) in accordance with forms and instructions. Any partnership interest that is designated as a QPI remains a QPI unless and until it no longer meets the requirements of paragraph (c)(2)(i) or (ii) of this section. For example, if an organization designates a directly-held partnership interest that meets the requirements of the de minimis rule as a QPI in one taxable year, the organization cannot, in the next taxable year, use NAICS 2-digit codes to describe the partnership trades or businesses that are unrelated trades or businesses with respect to the organization unless the directly-held partnership interest fails to meet the requirements of both the de minimis test and the participation test (after application of the grace period described in paragraph (c)(6) of this section, if appropriate).

(3) *De minimis test.* A partnership interest is a QPI that meets the requirements of the de minimis test if the organization holds directly (within the meaning of paragraph (c)(2)(i) of this section) or indirectly (within the meaning of paragraph (c)(2)(ii) of this section) no more than 2 percent of the profits interest and no more than 2 percent of the capital interest during the organization's taxable year with which or in which the partnership's taxable year ends.

(4) *Participation test*—(i) *In general.* A partnership interest is a QPI that meets the requirements of the participation test if the organization holds directly (within the meaning of paragraph (c)(2)(i) of this section) or indirectly (within the meaning of paragraph (c)(2)(ii) of this section) no more than 20 percent of the capital interest during the organization's taxable year with which or in which the partnership's taxable year ends and the organization does not significantly participate in the partnership within the meaning of paragraph (c)(4)(iii) of this section.

(ii) *Combining related interests.* When determining an organization's percentage interest in a partnership for purposes of paragraph (c)(4)(i) of this section, the interests of a supporting organization (as defined in section 509(a)(3) and § 1.509(a)–4), other than a Type III supporting organization (as defined in § 1.509(a)–4(i)) that is not a parent of its supported organization, or of a controlled entity (as defined in section 512(b)(13)(D) and § 1.512(b)–1(l)) in the same partnership will be taken into account. For example, if an organization owns 10 percent of the capital interests in a partnership, and its Type I supporting organization owns an additional 15 percent capital interest in that partnership, the organization would not meet the requirements of the participation test because its aggregate percentage interest exceeds 20 percent (10 percent + 15 percent = 25 percent).

(iii) *Significant Participation.* An organization significantly participates in a partnership if—

(A) The organization, by itself, may require the partnership to perform, or may prevent the partnership from performing (other than through a unanimous voting requirement or through minority consent rights), any act that significantly affects the operations of the partnership;

(B) Any of the organization's officers, directors, trustees, or employees have rights to participate in the management of the partnership at any time;

(C) Any of the organization's officers, directors, trustees, or employees have rights to conduct the partnership's business at any time; or

(D) The organization, by itself, has the power to appoint or remove any of the partnership's officers or employees or a majority of directors.

(5) *Determining percentage interest*—(i) *Profits interest.* For purposes of the de minimis test described in paragraph (c)(3) of this section, an organization's profits interest in a partnership is determined in the same manner as its distributive share of partnership taxable income. See section 704(b) (relating to the determination of the distributive share by the income or loss ratio) and §§ 1.704–1 through 1.704–4.

(ii) *Capital interest.* For purposes of the de minimis test (described in paragraph (c)(3) of this section) and the participation test (described in paragraph (c)(4)(i) of this section), in the absence of a provision in the partnership agreement, an organization's capital interest in a partnership is determined on the basis of its interest in the assets of the partnership which would be distributable to such organization upon its withdrawal from the partnership, or upon liquidation of the partnership, whichever is the greater.

(iii) *Average percentage interest.* For purposes of the de minimis test (described in paragraph (c)(3) of this section) and the participation test (described in paragraph (c)(4)(i) of this section), an organization determines its percentage interest by taking the average of the organization's percentage interest at the beginning and the end of the partnership's taxable year, or, in the case of a partnership interest held for less than a year, the percentage interest held at the beginning and end of the period of ownership within the partnership's taxable year. For example, if an organization acquires an interest in a partnership that files on a calendar year basis in May and the partnership reports on Schedule K–1 (Form 1065) that the partner held a 3 percent profits interest at the date of acquisition but held a 1 percent profits interest at the end of the calendar year, the organization will be considered to have held 2 percent of the profits interest in that partnership for that year ((3 percent + 1 percent)/2).

(iv) *Reliance on Schedule K–1 (Form 1065).* When determining the organization's average percentage interest (described in paragraph (c)(5)(iii) of this section) in a partnership for purposes of the de minimis test (described in paragraph (c)(3) of this section) and the participation test (described in paragraph (c)(4) of this section), an organization may rely on the Schedule K–1 (Form 1065) (or its successor) it receives from the partnership if the form lists the organization's percentage

profits interest or its percentage capital interest, or both, at the beginning and end of the year. However, the organization may not rely on the form to the extent that any information about the organization's percentage interest is not specifically provided. For example, if the Schedule K–1 (Form 1065) an organization receives from a partnership lists the organization's profits interest as ''variable'' but lists its percentage capital interest at the beginning and end of the year, the organization may rely on the form only with respect to its percentage capital interest.

(6) *Changes in percentage interest.* A partnership interest that fails to meet the requirements of the de minimis test (described in paragraph (c)(3) of this section) or the participation test (described in paragraph (c)(4) of this section) because of an increase in percentage interest in the organization's current taxable year may be treated for the taxable year of the change as meeting the requirements of the test it met in the prior taxable year if—

(i) The partnership interest met the requirements of the de minimis test or participation test, respectively, in the organization's prior taxable year without application of this paragraph (c)(6);

(ii) The increase in percentage interest is solely due to the actions of one or more partners other than the organization; and

(iii) In the case of a partnership interest that met the requirements of the participation test in the prior taxable year, the interest of the partner or partners that caused the increase in paragraph (c)(6)(ii) of this section was not combined for the prior taxable year and is not combined for the taxable year of the change with the organization's partnership interest for purposes of paragraph (c)(4)(ii) of this section.

(7) *UBTI from the investment activities of organizations subject to section 512(a)(3).* For purposes of paragraph (c)(1) of this section, UBTI from the investment activities of an organization subject to section 512(a)(3) includes any amount that—

(i) Would be excluded from the calculation of UBTI under section 512(b)(1), (2), (3), or (5) if the organization were subject to section 512(a)(1);

(ii) Is attributable to income set aside (and not in excess of the set aside limit described in section 512(a)(3)(E)), but not used, for a purpose described in section 512(a)(3)(B)(i) or (ii); or

(iii) Is in excess of the set aside limit described in section 512(a)(3)(E).

(8) *Limitations*—(i) *Social clubs.* Paragraphs (c)(2) (regarding QPIs) and (c)(9) (transition rule for certain partnership interests) of this section do not apply to social clubs described in section 501(c)(7).

(ii) *General partnership interests.* Any partnership in which an organization, or an organization whose interest is combined with that organization's interest for purposes of paragraph (c)(4)(ii) of this section, is a general partner under applicable state law is not a QPI within the meaning of paragraph (c)(2) of this section, regardless of the organization's percentage interest. Such partnership interest cannot be a QPI for any organization or for any of the organizations whose interest is combined with that organization's interest for purposes of paragraph (c)(4)(ii) of this section.

(iii) *Application of other sections.* This paragraph (c) does not otherwise impact application of section 512(c) and the fragmentation rule under section 513(c).

(9) *Transition rule for certain partnership interests*—(i) *In general.* If a directly-held partnership interest acquired prior to August 21, 2018, is not a QPI, an organization may treat such partnership interest as a separate unrelated trade or business for purposes of section 512(a)(6) regardless of the number of unrelated trades or businesses directly or indirectly conducted by the partnership. For example, if an organization has a 35 percent capital interest in a partnership acquired prior to August 21, 2018, it can treat the partnership as a single trade or business even if the partnership's investments generated UBTI from lower-tier partnerships that were engaged in multiple trades or businesses. A partnership interest acquired prior to August 21, 2018, will continue to meet the requirement of this rule even if the organization's percentage interest in such partnership changes before the end of the transition period (see paragraph (c)(9)(iii) of this section).

(ii) *Exclusivity.* An organization may apply either the transition rule in paragraph (c)(9)(i) of this section or the look-through rule in paragraph (c)(2)(ii) of this section, but not both, to a partnership interest described in paragraph (c)(9)(i) of this section that also qualifies for application of the look-through rule described in paragraph (c)(2)(ii).

(iii) *Transition period.* An organization may rely on this transition rule until the first day of the organization's first taxable year beginning after December 2, 2020.

(d) *Income from certain controlled entities*—(1) *Specified payments from controlled entities.* If an organization (controlling organization) controls another entity (within the meaning of section 512(b)(13)(D)) (controlled entity), all specified payments (as defined in section 512(b)(13)(C)) received by a controlling organization from that controlled entity are treated as gross income from a separate unrelated trade or business for purposes of paragraph (a) of this section. If a controlling organization receives specified payments from two different controlled entities, the payments from each controlled entity are treated as a separate unrelated trade or business. For example, a controlling organization that receives rental payments from two controlled entities has two separate unrelated trades or businesses, one for each controlled entity. The specified payments from a controlled entity are treated as gross income from one trade or business regardless of whether the controlled entity engages in more than one unrelated trade or business or whether the controlling organization receives more than one type of specified payment from that controlled entity.

(2) *Certain amounts derived from controlled foreign corporations.* All amounts included in UBTI under section 512(b)(17) are treated as income derived from a separate unrelated trade or business for purposes of paragraph (a) of this section.

(e) *S corporation interests*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, if an organization owns stock in an S corporation (S corporation interest), such S corporation interest is treated as an interest in a separate unrelated trade or business for purposes of paragraph (a) of this section. Thus, if an organization owns two S corporation interests, neither of which is described in paragraph (e)(2) of this section, the exempt organization reports two separate unrelated trades or businesses, one for each S corporation interest. The UBTI from an S corporation interest is the amount described in section 512(e)(1)(B).

(2) *Exception for a qualifying S corporation interest.* Notwithstanding paragraph (e)(1) of this section, an organization may aggregate its UBTI from an S corporation interest with its UBTI from other investment activities (described in paragraph (c)(1) of this section) if the organization's ownership interest in the S corporation meets the criteria for a QPI as described in paragraph (c)(2)(i) of this section (substituting ''S corporation'' for ''partnership'' and ''shareholder'' or ''shareholders'' for ''partner'' or ''partners,'' as applicable, throughout paragraphs (c)(2)(i), (c)(3), (c)(4), (c)(5)(iii), (c)(5)(iv), and (c)(6) of this

section; ''no more than 2 percent of stock ownership'' for ''no more than 2 percent of the profits interest and no more than 2 percent of the capital interest'' in paragraph (c)(3) of this section; ''no more than 20 percent of stock ownership'' in place of ''no more than 20 percent of the capital interest'' in paragraph (c)(4)(i) of this section; and ''Schedule K–1 (Form 1120–S)'' for ''Schedule K–1 (Form 1065)'' for purposes of paragraph (c)(5)(iv) of this section). Paragraphs (c)(5)(i) and (c)(5)(ii) do not apply for purposes of determining an organization's ownership interest in an S corporation; rather, the average percentage stock ownership determined under paragraph (c)(5)(iii) of this section applies for purposes of this paragraph (e)(2). For purposes of paragraph (c)(5)(iv) of this section, an organization can rely on the Schedule K–1 (Form 1120–S) (or its successor) it receives from the S corporation only if the form lists information sufficient to determine the organization's percentage of stock ownership for the year. A Schedule K–1 (Form 1120–S) that reports ''zero'' as the organization's number of shares of stock in either the beginning or end of the S corporation's taxable year does not list information sufficient to determine the organization's percentage of stock ownership for the year. The grace period described in paragraph (c)(6) of this section applies to changes in an exempt organization's percentage of stock ownership in an S corporation.

(f) *Allocation of deductions.* An organization must allocate deductions between separate unrelated trades or businesses using the method described in § 1.512(a)–1(c).

(g) *Total UBTI*—(1) *In general.* The total UBTI of an organization with more than one unrelated trade or business is the sum of the UBTI computed with respect to each separate unrelated trade or business (as identified under paragraph (a)(2) of this section and subject to the limitation described in paragraph (g)(2) of this section), less a charitable contribution deduction, an NOL deduction for losses arising in taxable years beginning before January 1, 2018 (pre-2018 NOLs), and a specific deduction under section 512(b)(12), as applicable.

(2) *UBTI not less than zero.* For purposes of paragraph (g)(1) of this section, the UBTI with respect to any separate unrelated trade or business identified under paragraph (a)(2) of this section cannot be less than zero.

(h) *Net operating losses*—(1) *In general.* For taxable years beginning after December 31, 2017, an exempt organization with more than one unrelated trade or business determines the NOL deduction allowed by sections 172(a) and 512(b)(6) separately with respect to each of its unrelated trades or businesses. Accordingly, if an exempt organization has more than one unrelated trade or business, § 1.512(b)–1(e) applies separately with respect to each such unrelated trade or business.

(2) *Coordination of pre-2018 and post-2017 NOLs.* An organization with pre-2018 NOLs, and with losses arising in a taxable year beginning after December 31, 2017 (post-2017 NOLs), deducts its pre-2018 NOLs from total UBTI before deducting any post-2017 NOLs with regard to a separate unrelated trade or business against the UBTI from such trade or business. Pre-2018 NOLs are taken against the total UBTI as determined under paragraph (g) of this section in a manner that allows for maximum utilization of post-2017 NOLs in a taxable year. For example, an organization could choose to allocate all of its pre-2018 NOLs to one of its separate unrelated trade or business or it could allocate its pre-2018 NOLs ratably among its separate unrelated trades or businesses, whichever results in the greatest utilization of the post-2017 NOLs in that taxable year.

(3) *Treatment of NOLs upon the termination, sale, exchange, or other disposition of a separate unrelated trade or business.* After offsetting any gain resulting from the termination, sale, exchange, or disposition of a separate unrelated trade or business, any NOL remaining is suspended. However, the suspended NOLs may be used if that previous separate unrelated trade or business is later resumed or if a new unrelated trade or business that is accurately identified using the same NAICS 2-digit code as the previous separate unrelated trade or business is commenced or acquired in a future taxable year.

(4) *Treatment of NOLs when the identification of a separate unrelated trade or business changes*—(i) *In general.* For purposes of section 512(a)(6) and this section, a separate unrelated trade or business for which the appropriate identification (within the meaning of paragraph (a) of this section) changes is treated as if the originally identified separate unrelated trade or business is terminated and a new separate unrelated trade or business is commenced. None of the NOLs from the previously identified separate unrelated trade or business will be carried over to the newly identified separate unrelated trade or business. For example, if the nature of a separate unrelated trade or business changes such that it is more accurately described by another NAICS 2-digit code, the separate unrelated trade or business is treated as a new separate unrelated trade or business with no NOLs. The change in identification may apply to all or a part of the originally identified separate unrelated trade or business. If the change in identification applies to the originally identified separate trade or business in its entirety, any NOLs attributable to that separate unrelated trade or business are suspended in accordance with paragraph (h)(3) of this section. If the change in identification applies to the originally identified separate unrelated trade or business in part, the originally identified separate unrelated trade or business that is not changing retains the full NOLs attributable to the originally identified separate unrelated trade or business, without allocation to the portion that became a newly identified separate unrelated trade or business. This paragraph (h)(4) also applies to each QPI that becomes a non-QPI. In this case, any NOLs attributable to the QPI that became a non-QPI are retained with the organization's investment activities described in paragraph (c) of this section.

(ii) *Exception for non-material changes.* In the case of a separate unrelated trade or business that is accidentally identified using the wrong NAICS 2-digit code or if an organization has determined that a separate unrelated trade or business that has not materially changed is more accurately identified by another NAICS 2-digit code, any NOL attributable to the originally identified separate unrelated trade or business becomes an NOL of the newly identified separate unrelated trade or business.

(iii) *Effective date of change in identification.* A change in identification described in this paragraph (h)(4) is effective on the first day of the taxable year in which the change in identification is made. Accordingly, the newly identified separate unrelated trade or business is treated as commencing on this date.

(iv) *Examples*—(A) *In general.* The following examples illustrate the rules described in this paragraph (h)(4).

(B) *Example 1. Erroneous code*—(*1*) Organization G is described in section 501(c) and is exempt from Federal income tax under section 501(a). In addition to its investment activities, Organization G has two separate unrelated trades or businesses—Q and R—that are identified with different NAICS 2-digit codes. Both Q and R have NOLs carried over from post-2017 taxable years.

(*2*) In Year 2 (a post-2017 taxable year), Organization G realizes that it

accidentally used the wrong NAICS 2-digit code to identify R. The NOLs attributable to R under the old NAICS 2-digit code become the NOLs of R under the new NAICS 2-digit code as of the first day of Year 2.

(C) *Example 2. Material change*—(*1*) Same facts as *Example 1,* except assume that, in addition to its investment activities, Organization G has three separate unrelated trades or businesses—Q, R, and S—that are identified with different NAICS 2-digit codes. Q, R, and S all have NOLs carried over from post-2017 taxable years.

(*2*) Organization G changes the NAICS 2-digit code identifying R to the same NAICS 2-digit code identifying S because the nature of the unrelated trade or business materially changed. Any post-2017 NOLs attributable to R are suspended (see paragraph (h)(4)(i) of this section). Organization G now has two separate unrelated trades or businesses—Q and S—as of the first day of Year 2.

(D) *Example 3. Partial material change.* Same facts as *Example 1,* except assume that Organization G determines that a part of R has materially changed such that R should be identified as two separate unrelated trades or businesses—R1 and R2. R1 retains the NAICS 2-digit code originally identifying R, and R2 is identified with a new NAICS 2-digit code that is not the same NAICS 2-digit code identifying Q. R2 is treated as a new separate unrelated trade or business with no NOLs as of the first day of Year 2. Any post-2017 NOLs attributable to R remain with R1.

(E) *Example 4. QPI to non-QPI*—(*1*) Same facts as *Example 1,* but assume that Organization G has a partnership interest in T that was, for prior taxable years, a QPI included with Organization G's investment activities. In Year 3 (a post-2017 taxable year), Organization G acquires more than 20 percent of the capital interests in T. The grace period described in paragraph (c)(6) of this section does not apply because the increase in percentage interest was not due to the actions of other partners.

(*2*) T conducts two trade or business activities that are unrelated trade or business activities with respect to Organization G—T1 and T2. Both T1 and T2 will be treated as new separate unrelated trades or business as of the first day of Year 2. Organization G identifies T1 with the same NAICS 2-digit code used to identify Q and T2 with a NAICS 2-digit code that is different than the NAICS 2-digit codes used to identify Q and R. In addition to its investment activities, Organization G has three separate unrelated trades or businesses—Q, R, and T2. Any post-2017 NOLs attributable to the QPI remain with Organization G's other investment activities separate unrelated trade or business.

(i) *Applicability dates.* This section is applicable to taxable years beginning on or after December 2, 2020. Taxpayers may choose to apply this section to taxable years beginning on or after January 1, 2018, and before December 2, 2020.

■ **Par. 6.** Section 1.512(b)–1 is amended by:

■ 1. Revising paragraph (a)(1).

■ 2. Adding a sentence to the end of paragraph (a)(3).

■ 3. Adding paragraph (e)(5).

■ 4. Adding paragraphs (g)(4) and (5).

The revisions and additions read as follows:

§ 1.512(b)–1 Modifications.

(a) * * *

(1) * * * Dividends (including an inclusion of subpart F income under section 951(a)(1)(A) or an inclusion of global intangible low-taxed income (GILTI) under section 951A(a), both of which are treated in the same manner as a dividend for purposes of section 512(b)(1)), interest, payments with respect to securities loans (as defined in section 512(a)(5)), annuities, income from notional principal contracts (as defined in § 1.837–7 or regulations issued under section 446), other substantially similar income from ordinary and routine investments to the extent determined by the Commissioner, and all deductions directly connected with any of the foregoing items of income must be excluded in computing unrelated business taxable income.

* * * * *

(3) * * * The exclusion under paragraph (a)(1) of this section of an inclusion of subpart F income under section 951(a)(1)(A) or an inclusion of GILTI under section 951A(a) from income (both inclusions being treated in the same manner as dividends) is applicable to taxable years beginning on or after December 2, 2020. However, an organization may choose to apply this exclusion to taxable years beginning before December 2, 2020.

* * * * *

(e) * * *

(5) See § 1.512(a)–6(h) regarding the computation of the net operating loss deduction when an organization has more than one unrelated trade or business.

* * * * *

(g) * * *

(4) The term *unrelated business taxable income* as used in section 512(b)(10) and (11) refers to unrelated business taxable income after application of section 512(a)(6).

(5) Paragraph (g)(4) of this section is applicable to taxable years beginning on or after December 2, 2020. Taxpayers may choose to apply this section to taxable years beginning on or after January 1, 2018, and before December 2, 2020.

* * * * *

■ **Par. 7.** Section 1.513–1 is amended by:

■ 1. Revising the third and fourth sentence in paragraph (a).

■ 2. Redesignating paragraphs (f) and (g) as paragraphs (g) and (h).

■ 3. Adding new paragraph (f).

■ 4. Adding a sentence to the end of newly redesignated paragraph (h).

The revisions and additions read as follows:

§ 1.513–1 Definition of unrelated trade or business.

(a) * * * For certain exceptions from this definition, see paragraph (e) of this section. For a special definition of *unrelated trade or business* applicable to certain trusts, see paragraph (f) of this section. * * *

* * * * *

(f) *Special definition of* ''*unrelated trade or business*'' *for trusts.* In the case of a trust computing its unrelated business taxable income under section 512 for purposes of section 681, or a trust described in section 401(a) or section 501(c)(17), which is exempt from tax under section 501(a), section 513(b) provides that the term *unrelated trade or business* means any trade or business regularly carried on by such trust or by a partnership of which it is a member. This definition also applies to an individual retirement account described in section 408 that, under section 408(e), is subject to the tax imposed by section 511.

* * * * *

(h) * * * Paragraph (f) of this section applies to taxable years beginning on or after December 2, 2020.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: November 13, 2020.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2020–25954 Filed 11–30–20; 4:15 pm]

BILLING CODE 4830–01–P

Reader Aids

Federal Register

Vol. 85, No. 232

Wednesday, December 2, 2020

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, DECEMBER

76949–77342 1
77343–77984 2

CFR PARTS AFFECTED DURING DECEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
10121 77343

5 CFR

Proposed Rules:
2641 77014

8 CFR

Proposed Rules:
103 77016
235 77016

10 CFR

Proposed Rules:
430 77017

12 CFR

3 77345
4 77345
52 77345
208 77345
211 77345
212 77345
217 77345
225 77345
235 77345
238 77345
304 77345
324 77345
337 77345
347 77345
348 77345
614 77364

14 CFR

39 ..... 76949, 76951, 76953, 76955
71 76958

16 CFR

Proposed Rules:
801 ..... 77042, 77053
802 ..... 77042, 77053
803 ..... 77042, 77053

26 CFR

1 ..... 76960, 76976, 77365, 77952
602 77952

28 CFR

26 76979

33 CFR

Proposed Rules:
165 77093

36 CFR

Proposed Rules:
1224 77095
1225 77095
1236 77095

40 CFR

63 77384
320 77384

42 CFR

411 77491
486 77898
512 77404
1001 77684
1003 77684

45 CFR

153 76979

50 CFR

635 77007
665 77406
679 77406

Proposed Rules:
17 ..... 77108, 77408

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List November 3, 2020

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to *https://listserv.gsa.gov/cgi-bin/wa.exe?SUBED1=PUBLAWS-L&A=1*

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.